

IMPROVING COMMUNICATIONS FOR PATIENT ACCRUAL IN CLINICAL
TRIALS TO PROMOTE INFORMED HEALTH DECISION MAKING

A Dissertation

Presented to the Faculty of the Graduate School
of Cornell University

In Partial Fulfillment of the Requirements for the Degree of
Doctor of Philosophy

by

Zheng Yang

August 2009

© 2009 Zheng Yang

IMPROVING COMMUNICATIONS FOR PATIENT ACCRUAL IN CLINICAL TRIALS TO PROMOTE INFORMED HEALTH DECISION MAKING

Zheng Yang, Ph. D.

Cornell University 2009

This dissertation applies a risk communication theoretical framework, the Risk Information Seeking and Processing Model (RISP), to address a health communication challenge that aims to promote informed decision making about clinical trial enrollment. A review of theoretical development and empirical evidence suggests several pathways to refine the model, which guides subsequent analyses. To compare the general patterns of information seeking among prospective healthy volunteers and cancer patients and their caregivers, Chapter 3 tests how risk perceptions, affective responses, and normative beliefs motivate routine and non-routine information seeking. Specifically focused on prospective healthy volunteers, Chapter 4 examines the applicability of the central part of the RISP model to account for more active information seeking and higher-level information processing. Linking the RISP model to the Theory of Planned Behavior, Chapter 5 investigates how cognitive processing styles, affective responses, and normative beliefs influence cancer patients' general attitudes and intentions to enroll in a future trial. Through a comparative analysis using multiple-sample structural equation modeling, the final substantive chapter demonstrates that even though cognitive processing styles and normative beliefs mainly shape prospective healthy volunteers' decisions about clinical trial enrollment, emotional factors have a greater impact on cancer patients and their caregivers. Since the most fundamental mechanism that the RISP model proposes, a cognitive need to

achieve information sufficiency, fails to influence information seeking and processing throughout the different chapters, the final chapter proposes an adjusted version of the model that allows for a change in contextualization across research settings. Findings from this dissertation also offer evidence-based recommendations to improve patient accrual for clinical trials.

BIOGRAPHICAL SKETCH

Zheng Yang was born in Urumqi, Xinjiang, in the Northwestern part of China. She completed an undergraduate degree in journalism (2003) at Fudan University in Shanghai, China, and a Master of Arts degree in Communication (2005) at Marquette University in Milwaukee, Wisconsin. As a journalism student, she worked at the prestigious news program *News Probe* at the China Central Television (CCTV) and several daily newspapers in mainland China. She wrote for the *Cornell Chronicle* as a freelance writer, worked as a graduate resident fellow at the *Carl Becker House*, and performed with the *Amber Chinese Dance Troupe* during her days at Cornell University.

To my parents, for their unconditional love.

ACKNOWLEDGMENTS

The past four years at Cornell University have been a rewarding experience that enabled me to grow intellectually and personally. I feel fortunate for all the opportunities that Cornell has given me, which helped me to learn new skills, meet interesting people, and sketch out future plans.

I am grateful for the wisdom that faculty here at Cornell have shared with me, through formal instruction, research meeting, or teaching supervision. The staff members of our department have provided generous support whenever I needed their help. My student colleagues, especially my office mates, have always surrounded me with care and encouragement, and I will treasure their friendship.

My special committee has made the writing and defense of my dissertation an enjoyable process. I am thankful to Jeff Hancock for his insightful comments and careful reading of my dissertation draft. The final product was a more valuable piece because he insisted that I should go that one step further. Cliff Scherer was the first faculty member to involve me in a research project. He has helped me to broaden my thinking about risk communication issues, and his passion for teaching will continue to inspire me in my future career. As the external member, Stephen Hilgartner not only brought in new perspectives that enriched my dissertation research, but also impelled me to strive for greater depth in my intellectual pursuit.

Even though the training at Cornell has exceeded all my expectations, I owe a big part of my success to my former advisor, Robert Griffin. He introduced me to risk communication research, taught me all the necessary skills to be an independent scholar, and motivated me to develop a career in academia. I will never forget the picture of the McGraw Tower that he printed on my comprehensive exam for my master's degree. I am the researcher I am today because he has always had faith in me.

As a great mentor and friend, Katherine McComas has my deepest gratitude

and respect for the instrumental role that she has played in shaping my career. She gave me the opportunity to develop a grant proposal that led to the financial support for this dissertation research. She included me in a variety of research projects that broadened my horizon and helped me to establish my own network in the research community. Katherine is a role model to me in every aspect of life, and I am honored that our names have, and will be, listed together on our publications.

Finally, my parents have my most profound appreciation and love because they have always been there for me, albeit not always close to me physically. Over the past three months, they have nourished me with delicious food and joyful company. I hope this dissertation, along with any other achievement I could claim at Cornell, will make them proud.

My indebtedness to all of those mentioned above and many others for whom I am grateful in heart is plentiful. As always, however, I take full responsibility for whatever errors may have escaped me or whatever biases, hidden or apparent, that remain in this dissertation.

TABLE OF CONTENTS

BIOGRAPHICAL SKETCH	iii
DEDICATION	iv
ACKNOWLEDGMENTS	v
LIST OF FIGURES	viii
LIST OF TABLES	ix
CHAPTER 1: Introduction	1
CHAPTER 2: Applying the RISP Model	11
CHAPTER 3: Information Seeking related to Clinical Trial Enrollment	36
CHAPTER 4: Motivation for Health Information Seeking and Processing	59
CHAPTER 5: From Information Processing to Behavioral Intentions	85
CHAPTER 6: Comparing Clinical Trial Enrollment Decisions	108
CHAPTER 7: Overall Conclusion and Future Research	132
APPENDIX 1: IRB Approval Application	149
APPENDIX 2A: National Sample Questionnaire	158
APPENDIX 2B: LLS Sample Questionnaire	163
REFERENCES	169

LIST OF FIGURES

Figure 2.1 Model of Risk Information Seeking and Processing	11
Figure 3.1 Augmented Model of Risk Information Seeking	39
Figure 3.2 Interaction Graph: Informational Subjective Norms by Sample	50
Figure 3.3 Interaction Graph: Negative Affects by Sample	51
Figure 3.4 Interaction Graph: Risk Judgment by Sample	52
Figure 4.1 Results for the Conceptual Model (National Sample SEM)	75
Figure 6.1 Results for the Conceptual Model (Multiple-Sample SEM)	124
Figure 7.1 Adjusted Risk Information Seeking and Processing Model	140

LIST OF TABLES

Table 2.1 Overview of RISP Model Results	27
Table 3.1 Hypotheses for Routine/Non-Routine Information Seeking	42
Table 3.2 OLS Regression Results for Information Seeking	47
Table 4.1 Correlation of Key Seeking/Processing Measures with Attention	70
Table 4.2 Descriptive Statistics (SEM - National Sample)	73
Table 4.3 Summary of Fit Indicators (SEM - National Sample)	74
Table 5.1 Correlation of Key Processing Measures with Attention	94
Table 5.2 OLS Regression Results for Attitudes and Behavioral Intention	99
Table 6.1 Descriptive Statistics (Multiple Sample SEM - National Sample)	120
Table 6.2 Descriptive Statistics (Multiple Sample SEM - LLS Sample)	121
Table 6.3 Summary of Fit Indicators (Multiple Sample SEM)	122

CHAPTER 1

INTRODUCTION

Health communication scholars have long argued for theory-based research that offers practical implications for health interventions and public campaigns. To solve communication problems related to a variety of health issues, a number of theoretical frameworks have been proposed to depict the process in which people access and absorb health-related information to guide their behaviors. Some of them focus on psychological mechanisms that motivate health-related information seeking and retention (Afifi & Weiner, 2004; Brashers, Goldsmith, & Hsieh, 2002; Rimal & Real, 2003), while others adopt a more sense-making approach, taking into account the background and context of health information acquisition (Johnson, 1997). These theories primarily explain how the interplay of uncertainty, expectancy, and efficacy could motivate or hinder one's information seeking; few of them, however, connect communication behaviors with subsequent health decision making related to attitude formation and behavior change. In other words, communication researchers often expect that greater exposure to health information will ameliorate individuals' decision making process. As Brashers (2001) pointed out, however, greater exposure to health information could at times distress individuals who suffer from chronic illnesses.

In viewing these theories, even though they mostly adopt a socio-psychological perspective when examining information seeking, few evidently describe the cognitive and evaluative processes that push individuals from having a tepid interest in health-related information to sensing an uncertainty or discrepancy that needs to be resolved in order to deal with an important health issue. Nonetheless, this latter state, the awareness of an uncertainty or discrepancy, often constitutes the starting point for many of these existing theories (Brashers, 2001). Further, even though some of these

theories acknowledge the impact of emotion on rational decision making (Afifi & Weiner, 2004), they rarely grant enough attention to emotions' activating effects that could directly motivate information seeking and processing activities. In comparison, risk communication theories such as the "affect heuristics" framework (Slovic, Finucane, Peters, & MacGregor, 2005) and the "risk as feelings" hypotheses (Loewenstein, Weber, Hsee, & Welch, 2001) have highlighted the importance of emotions when we study social phenomena that involve risk judgment and reactions to an uncertain situation. Since risk and uncertainty are routinely part of the vocabulary used to describe health communication challenges, it is essential to investigate how emotions, directly or indirectly through the influence on analytical reasoning, could impact individuals' health-related information management.

Examining these theoretical frameworks together, another important, yet often ignored, aspect is the socio-cultural environment in which information seeking activities occur. Johnson's (1997) model and Brashers' (2001) theories of uncertainty management both hint at the impact of relational concerns in shaping individuals' beliefs about information seeking. However, neither of them offers specific propositions that allow this impact to be assessed empirically. Similarly, within its scope condition of active cognitive engagement in an interpersonal context, Afifi and Weiner's (2004) theory of motivated information management (TMIM) accounts for influence of the information provider. However, compared to their detailed illustration of how information seekers evaluate information related to outcome and efficacy, it is less clear how the feedback from information providers affect information seekers' ultimate decisions. In addition, normative influences from other important people in one's social network, including those who are not key information providers, is not reflected.

As a communication researcher who stands astride the fields of health

communication and risk communication, I often pay attention to theoretical models that overlap in their basic dynamics because, fundamentally, they are put forward to account for similar phenomena. When researchers migrate across these disciplines, a more comprehensive conceptual framework might offer a more thorough and cohesive portrayal of critical issues that impede effective communications of health and risk topics. The present series of studies attempt to assess one such theoretical model, the Risk Information Seeking & Processing (RISP) model (Griffin, Dunwoody, & Neuwirth, 1999). Based on the Heuristic-Systematic Model (HSM, Eagly & Chaiken, 1993) and the Theory of Planned Behavior (TPB, Ajzen, 1988), the RISP model originates from risk communication research, but over the last decade, it has guided research across various disciplines such as risk, health, and environmental communication. Empirical evidence from these studies, for the most part, has provided support for its key propositions. Chapter 2 provides a review of this research.

The remainder of the dissertation focuses on testing and extending the RISP model to the context of clinical trial enrollment decisions. Presenting a unique research context for this investigation are communication issues related to clinical trial enrollment. Since risk and uncertainty are inevitable parts of any discussion related to clinical trial participation, I believed that the RISP model would be an appropriate framework. This conjecture, however, is tested through subsequent analyses. To make this investigation even more interesting, I collected data from two samples for the purpose of comparative analysis. Information gathered through a random digit dial telephone survey of the U.S. adult population, accompanied by a telephone survey of members of the Leukemia & Lymphoma Society (LLS), allows me to draw evidence-based recommendations to improve the dissemination of information related to clinical trial enrollment. Applying the RISP model to study informed decision making related to clinical trial enrollment, I intend to offer my insight from a communication

perspective to solve a problem that has perplexed medical researchers – the low enrollment rate for clinical trial studies. Therefore, theoretical pursuit and practical need complement each other in forming this research endeavor.

Research Context

Low patient accrual in clinical trials poses a serious concern for the advancement of medical science in the United States. As the National Cancer Institute (2006) states on its clinical trial information portal, less than five percent of adults diagnosed with cancer each year get treated through enrollment in a clinical trial. With broader enrollment, the effort to find newer and better ways to treat and prevent cancer might be swifter. To address low enrollment, hundreds of studies have sought to identify and overcome barriers to enrollment, and there are several excellent reviews of this literature (Abraham, Young, & Solomon, 2006; Mills et al., 2006). Although emerging from several disciplines, some consistent findings are present:

Among patient-related barriers to enrollment include a lack of awareness and knowledge about clinical trials (Baquet, Commiskey, Mullins, Mishra, 2006; Giuliano et al., 2000; Harris, Gorelick, Samuels, Bempong, 1996); patient attitudes toward clinical trials, including fear of randomization and fear of side-effects (Madsen, Holm, & Riis, 2007; Sharp et al., 2006); logistical problems, including travel to study locations or access to childcare (Avis, Smith, Link, Hortobagyi, & Rivera, 2006); and trust or distrust of physicians and trial researchers (Grady et al., 2006; Jenkins & Fallowfield, 2000; Mills et al., 2006). Alternatively, patient incentives have included perceived personal benefits (Wright et al., 2004), scientific merit of the study (Wright, Crooks, Ellis, Mings, & Whelan, 2002) and feelings of altruism (Peel, Parry, Douglas, & Lawton, 2006).

Physician barriers influencing enrollment have included physicians' knowledge, attitudes, and motivations to enroll patients in clinical trials (Castel,

Negrier, & Boissel, 2006; Comis, Miller, Aldige, Krebs, Stoval, 2003; Fallowfield, Ratcliffe, & Souhami, 1997; Mannel et al., 2003; Somkin et al., 2005). Research has also found that the manner by which physicians communicate with their patients about clinical trials plays a key role (Albrecht, Blanchard, Ruckdeschel, Coover, & Strongbow, 1999; Albrecht et al., 2003; Grant, Cissna, & Rosenfeld, 2000; Jenkins, Fallowfield, Souhami, Sawtell, 1999). Studies have also specifically targeted communication related to explaining randomization and obtaining informed consent (Fallowfield et al., 1998; Hutchison & Campbell, 2002; Kodish et al., 2004; Stryker, Wray, Emmons, Winer, & Demetri, 2006). Finally, institutional barriers to enrollment have also been identified, including a lack of availability of clinical trials for certain patients, or the disqualification of other patients (Comis et al., 2003).

Communication Perspective

Despite the centrality of communication to many of these challenges, communication research is largely absent from this literature, which suggests the importance and necessity for the current series of studies. Given the theoretical outlook of this research project, findings from these studies will, in return, contribute to the development of communication theories on a broader scale.

Among several theoretical frameworks that focus on motivations for communication behavior, the RISP model is unique in that it examines within-audience variance in risk-related information seeking and processing accounted for by a number of important psychological and social mechanisms. For instance, concepts reflected in the RISP model include causal attribution, self-efficacy, subjective norm, judgmental confidence, and general attitudes towards different information channels. The RISP model also evaluates the impact of individual characteristics such as education, political philosophy, current knowledge about a particular issue, and information gathering capacity. Informed by the main propositions of the RISP model,

the series of studies presented here not only examine its overall applicability to this health communication issue but also extend the model in several important ways.

First, the RISP model includes an affective component, termed as affective responses, which allows for a comparison between the impact of negative and positive emotions that might be associated with perceived risk. Several studies reported here contained a comparison of possible negative and positive emotions related to clinical trial enrollment and their relative impact on individuals' communication behavior. Second, recent development based on the RISP model (Kahlor, 2007, for instance) has argued for a revisit to its theoretical foundation to explore the linkage between the RISP model and the TPB. This proposition also guided a number of studies reported here. Third, based on new findings accumulated in recent years (for instance, Huurne, Griffin, & Gutteling, forthcoming; Griffin et al., 2008; Kahlor et al., 2006), the alignment of key cognitive and affective components of the RISP model is reassessed with structural equation modeling. Lastly, the RISP model was initially developed to examine motivations behind seeking and processing behaviors related to the mass media. Since most of the communications of clinical trial enrollment usually occur at the interpersonal level, or through new media formats such as health website, applying the RISP model to these scenarios could also attest to its ecological validity.

Outline of Chapters

Immediately following this introduction, the second chapter provides an overview of the RISP model and its development over the past decade. This chapter mainly highlights its applicability to a medical decision making context, specifically related to the current research project. Based on a synopsis of past findings, it then calls attention to the possibility of revising the model to better depict key factors that work together to motivate higher-level information seeking and processing. The chapter notes that existing research has mainly tested different parts of the RISP model

step-by-step but has insufficiently examined the model in its entirety. More importantly, the RISP model was constructed to serve as a theoretical linkage between individuals' mental calculation of and response to a potential risk, their submission to social influences, and their intention to engage in information seeking and processing behavior. Inspired by Kahlor's (2007) proposition of an augmented RISP model, the second chapter argues that the RISP model should go beyond the communication behaviors to explore what comes after information seeking and processing. Several important features of the model justify this extension. First, within the RISP model, key motives that shape attitudinal positions, as proposed by the HSM, such as defensive motivation and impression management, could be tested together with other individual and social factors that influence risk-related behaviors. Second, the tie between the RISP model and the TPB was not only posited in Griffin et al.'s seminal piece (1999), but was also shown to be a robust linkage across a variety of research settings. Therefore, the chapter concludes by introducing the specific objectives of subsequent chapters in order to achieve this overarching goal.

In an effort to understand what motivates people to attend to information about clinical trial enrollment, the third chapter sets up ground work for subsequent chapters by depicting how healthy respondents and LLS respondents differ in their information seeking behaviors. Specifically, routine information seeking through the traditional mass media and non-routine information seeking through online sources were categorized separately. Informed by the augmented RISP model, general attitudes toward the behavior were assessed along with other RISP components. By testing interaction terms, group membership is found to moderate key relationships between routine and non-routine information seeking and negative emotions, risk judgment, as well as normative beliefs. Other variables examined in this chapter include positive emotions associated with clinical trial participation, general awareness, and the

tendency to rely on independent decisions.

Following this general comparison of information seeking behaviors across the two samples, the fourth chapter specifically focuses on the national sample because one goal of improving communications about clinical trial enrollment is to enhance awareness and understanding among the general public. Structural equation modeling is used to test the central part of the RISP model. This analysis highlights the role of optimism, as a type of affective response, in motivating information seeking and processing. Key results indicate that besides exerting an indirect influence on information seeking through motivating a cognitive need for more information, optimism also directly influences information seeking and processing. Similarly, informational subjective norms, as another key component of the RISP model, also have more direct influence on information seeking and processing. These results speak to the applicability of the RISP model to this health decision making context. In addition, major findings from this chapter warrant readjustment of the model and inform the accrual of healthy volunteers for clinical trial research.

Shifting gear back to cancer patients, the fifth chapter mainly tests the proposition that the RISP model could serve as an antecedent to the TPB. Specifically, the outcome variables of the RISP model, systematic and heuristic processing, are examined together with cancer patients' belief-based attitudes and behavioral intentions related to clinical trial enrollment. To explore other individual and social factors that might influence cancer patients' attitudes toward clinical trial enrollment, other RISP components are also included in subsequent analyses. Key results indicate that risk judgment and affective responses, especially optimistic feelings, have the most consistent relationships with cancer patients' attitudes and behavioral intentions related to clinical trial enrollment. Trust in doctors also significantly related to the positive attitudes toward clinical trials. These findings suggest that the RISP model

might have more constrained applicability as compared to the TPB in explaining cancer patients' motivations for clinical trial enrollment. However, certain components of the RISP model might be interesting additions to the TPB as they contribute to the formation of belief-based attitudes toward clinical trials.

As a comparative investigation, the sixth chapter presents findings from multiple-sample structural equation modeling analysis. To effectively link communication behaviors with actual decisions related to participation, data from the two samples are compared to reveal potential differences among healthy respondents and LLS members. Main results indicate that information processing strategies have less influence on attitudes and behavioral intentions among LLS respondents, as compared to the national sample. On the contrary, affective responses, especially optimistic feelings, play a bigger role in influencing attitudes and behavioral intentions among cancer patients and their caregivers. Surprisingly, normative beliefs have stronger total effects on healthy respondents' behavioral intentions related to clinical trial participation. The relationship between belief-based attitudes and behavioral intentions is also stronger in the national sample, as compared to the LLS sample. These results suggest that communication efforts focused on improving clinical trial enrollment should attempt to balance among providing information, using emotional appeals, and stressing social norms in order to achieve attitudinal and behavioral change in more effective ways.

Based on results from these studies, the final chapter discusses ethical and practical implications of the overall project, while at the same time it reevaluates my initial interest and passion to get involved in this research effort. Risk and health communication research is often positioned at a unique middle point. That is, we walk between scientist and experts who strive to produce and create new knowledge and members of the general public who are involved, willingly or unwillingly, in the

shaping of policy and the socio-cultural environment of our society. Therefore, the mission of the current project, albeit perhaps representing an ideal understanding of my duty as a communication researcher, is not to generate new ideas or more effective toolkits to recruit more healthy volunteers or cancer patients into clinical trial research. Quite the opposite, the ultimate goal is to detect what might urge more people to pay attention to information about clinical trial enrollment and equip themselves with basic knowledge and resources to deal with this issue. Once basic awareness is improved among the general public, it is more likely for ordinary citizens to engage in meaningful discussions with their primary care physicians or other medical experts about clinical trial opportunities that might benefit themselves or those who are important to them. Improved public knowledge and awareness about clinical trial research will ultimately benefit medical research as well. After all, it is more likely for medical researchers to obtain robust and meaningful results if those who participate in clinical studies come from a qualified pool of subjects who are well-informed and well prepared, rather than a group of professional “guinea pigs” who exchange their body and mind as medical commodities.

CHAPTER 2

APPLYING THE RISP MODEL TO STUDY MEDICAL DECISION MAKING RELATED TO CLINICAL TRIAL ENROLLMENT

The Risk Information Seeking and Processing (RISP) model, since its original proposition, has generated a dozen or so empirical analyses that produced a vast amount of evidence in support of the key relationships shown in the model (Figure 2.1). Initial analyses examined different parts of the model separately, while recent studies tend to evaluate the model in its entirety across different research contexts. To serve as a theoretical overview, this chapter first introduces key components of the RISP model as well as the relationships it posits. Then, based on a review of its development over the last decade, it concludes with suggestions of several potential pathways to enhance the model, which subsequently guide the following chapters.

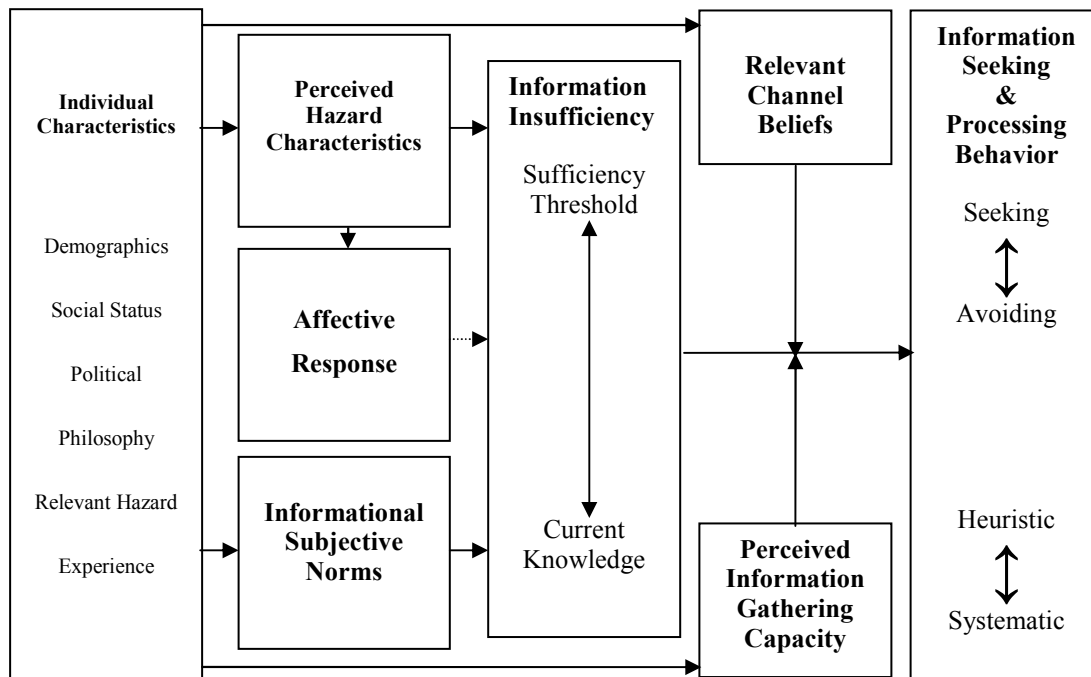


Figure 2.1
Risk Information Seeking and Processing Model (adapted from Griffin et al., 1999)

Theoretical Overview

According to Griffin et al. (1999), the RISP model offers a framework to depict what key factors might predispose individuals to seek and process relevant risk-related information in a more systematic or thoughtful manner. Consistent with the assumption of its theoretical foundation, the Heuristic-Systematic Model (HSM) (Eagly & Chaiken, 1993), the RISP model views information processing as an antecedent to attitude formation and behavior change. There has been empirical evidence showing that a deeper, more systematic way of information processing is positively related to stronger and more stable behavior-based beliefs related to environmental hazards (Griffin, Neuwirth, Giese, & Dunwoody, 2002). Recent development of the RISP model also includes an integration of additional key concepts from the TPB, investigating the utility of an augmented RISP model (Kahlor, 2007) to explain individuals' intention for information seeking about environmental risk. The current research project, as part of this continuous effort, returns this exploration to the domain of health communication, where the RISP model was first introduced.

Based on dual-processing theories, the RISP model suggests that active seeking and systematic processing of risk-related information are primarily motivated by one's psychological need for information sufficiency. This idea is largely adopted from the HSM's sufficiency principle, which suggests that "people will exert whatever effort is required to attain a 'sufficient' degree of confidence that they have satisfactorily accomplished their processing goals" (Eagly & Chaiken, p. 330). The motivating effect of the desire for information sufficiency (termed as information insufficiency hereafter) is moderated by individuals' capacity to gather relevant information and their assessment of the information source. According to Trumbo (2002), this framework is appropriate for communication studies because it forms

effective links between the questions of where people get information about a particular topic and how they deal with this information. Given the overarching goal of this research project, the empirical analyses presented here focus less on whether patients are capable of engaging in higher-level information processing because the ability to decode health information through a meaningful informed consent process warrants another discussion of its own. Rather, these studies are mainly interested in the part of the RISP model that addresses the issue of motivation.

Similar to other dual-processing theories, Eagly and Chaiken defined heuristic processing as “a limited mode of information processing that requires less cognitive effort and fewer cognitive resources” (p. 327). Systematic processing, in comparison, is a “relatively analytic and comprehensive treatment of judgment-relevant information” (Chen & Chaiken, 1999, p. 74). These two concepts resemble the “central route” and “peripheral route” as proposed in the Elaboration Likelihood Model (Petty & Cacioppo, 1986). However, as Chaiken and Stangor (1987) pointed out, HSM asserts that “persuasion is often mediated by simple decision rules that associate certain persuasion cues with message validity”, whereas ELM specifies motives that produce attitude change without generating active issue-relevant thinking (p. 593). Consistent with HSM’s assumptions, the RISP model’s focus on how information is integrated to affect beliefs and attitudes renders it applicable not only to persuasion settings but also to other situations in which people “gain new information about attitude objects or ruminate about information they already possess” (Eagly & Chaiken, p. 257).

Even though systematic processing is considered less superficial, a heuristic strategy has the mental and economic advantage of requiring a minimum of cognitive effort (Chaiken, 1980). Therefore, people tend to engage in heuristic processing unless motivated to adopt the more effortful strategy. Heuristic and systematic processing

could also occur at the same time (Dijksterhuis, Bos, Nordgren & Van Baaren, 2006). However, Chaiken (1980) pointed out that the heuristic strategy may be less reliable when used to judge message validity because an overreliance on simple decision rules may lead recipients to accept conclusions they might otherwise reject had they invested the time and cognitive resources to discover and scrutinize different arguments (p. 753). This notion seems particularly relevant to the present case of study. As compared to following routine regimen, the decision to participate in a clinical trial often requires more detailed risk and benefit assessment and more personal involvement in terms of decision making.

As Beauchamp and Childress (1994) mentioned, the informed consent to participate in a clinical trial should represent nothing less than an “autonomous authorization” by an individual. Therefore, even though the popular “informed judgment model” requires doctors to transfer the necessary expertise to their patients so that he or she could make an informed judgment (Charles, Gafni, & Whelan, 1999; Wright et al., 2004), it might be insufficient. That is to say, if no systematic evaluation of the information follows the knowledge transfer, it is unlikely that an individual will be able to reach a decision that works the best for him or her. Therefore, as health communication researchers, we need to take on this difficult task of promoting a more systematic way to process health information and greater involvement on the patient end.

The RISP model adopts HSM’s proposition of a sufficiency principle that is primarily based on judgmental confidence. This judgmental confidence, according to Eagly and Chaiken, particularly relates to the assessment of message validity, which they described as an *accuracy motivation*. Two additional motivations are also likely to trigger systematic processing. Specifically, defense motivation is based on one’s desire to form and hold beliefs that are consistent with his or her material interests and

fundamental values. Impression motivation refers to one's desire to express attitudes that help them meet their immediate social goals, such as getting along with others (Chen & Chaiken, 1999). Chaiken, Liberman, and Eagly (1989) propose that both defense motivation and impression motivation could lead to either heuristic or systematic processing, depending on the social contexts in which they function. For instance, when defense-motivated individuals receive information from an authority figure that is in line with their position, they may adopt heuristics such as the belief that expertise and specialized knowledge are always trustworthy. However, when the same defense-motivated individuals receive a similar message from a less-valued source, they may engage in further deliberation to reinforce their own belief. Similarly, even though following a simple decision rule such as "go with the consensus" sounds heuristic in nature, the desire to identify the consensus and reach conformity might generate greater information seeking and more effortful processing.

The RISP model alludes to these motivations through concepts such as relevant channel beliefs and informational subjective norms. Specifically, even though the conceptualization and measurement strategy associated with relevant channel beliefs are still under refinement, overall, this component describes whether or not individuals believe that a particular information channel could provide useful information, while at the same, be accessible and trustworthy. These notions mainly reflect the findings that people's habitual information processing strategies are influenced by their perceived images of the media (Kosicki & McLeod, 1990). Informed by Chaffee's (1986) cost-benefit analysis approach to explain information channel selection, Griffin et al. (2005) offered a more detailed account for this component, focusing on the perception that a particular information channel will contain information that is most relevant to individuals' processing task. Specifically related to the current research context, when there is some sort of power differentiation between information seekers

and information providers, such as between patients and physicians, it could be expected that relational factors such as trustworthiness might be more influential as compared to accessibility and usability. When facing an authority figure, defense motivation and impression management might be activated to drive individuals into more active seeking and processing of relevant information.

Informational subjective norms, a concept adopted from the TPB, reflect these alternative motivations even more closely. The RISP model has traditionally depicted this component as individuals' inclination to respond to social pressures or expectations that they should acquire sufficient information to deal with the risky situation. The reasoning is that people under greater normative influence from those who are important to them will be more likely to engage in information seeking and processing activities, and possibly, be more actively involved in the decision making process. This component of the RISP model takes into account potential influence from the surroundings in which communication behaviors occur. Thus, different from other similar theoretical models that are purely based on people's internal calculations, the RISP model has leeway to assess the impact of socio-cultural factors on people's motivations. Recent development has identified both direct and indirect influence from this variable on information seeking and processing, which will be discussed in greater detail later.

Besides informational subjective norms, other antecedents to information insufficiency include individuals' cognitive evaluations of and affective responses to a particular risk issue. Griffin et al. (1999) proposed that given the negative valence of risk perception, affective responses associated with it are most likely negative in nature. However, in their subsequent theorization, they recognized that positive responses such as hope could also constitute emotions engendered from a risk situation (Griffin et al., 2008). Social psychologists have long argued that both hope

and anxiety could originate from an appraisal that is based on an uncertain outcome (Ortony & Clore, 1981), whereas empirical evidence has shown emotions characterized by an uncertain appraisal to promote systematic processing (Tieden & Linden, 2001). Since uncertainty is an indisputable part of risk perception, it is reasonable to assume that emotions of a positive valence could also play a role in the RISP model.

In regards to the cognitive evaluation of risk, formally termed as perceived hazard characteristics in the RISP model, this component involves several distinct dimensions. Up until now, Griffin, Neuwirth, Dunwoody and Giese (2004) offered the most comprehensive description for this construct. Besides the broadly used measures of risk judgment based on subjective perception of the probability and severity of personal harm, two more relevant variables were included: personal control and institutional trust. Personal control deals with people's belief that they could do something to protect themselves or others. In contrast, institutional trust depicts one's willingness to rely on experts or authorities for protection (Siegret, Cvetkovich, & Roth, 2000). Later, informed by attribution theory (McGuire, 1974) and data indicating that different attribution styles shape risk perception in different ways (Kahlor et al., 2002), causal attribution was integrated into the RISP model as part of the perceived hazard characteristics component (Griffin et al., 2008). Viewing various RISP components together, in line with the current research context, individuals' general trust for physicians and medical researchers seem to fit better into the model as a measure for relevant channel beliefs. Given the complexity of potential risks involved in the clinical trial process, a generic assessment of risk perception might suit the current study well.

Lastly, at the deep background of the RISP model, demographic variables, past experience, political philosophy, and other sociocultural factors also contribute to

within-audience variations in terms of information need and information acquisition styles. Past research has found that women, minorities, those who are younger, and those who have had previous experience generally report slightly more informational insufficiency. Education level has also been associated with current knowledge and informational gathering capacity. Overall, however, these variables have accounted for a rather minimal amount of variance in the dependent variables.

Theoretical Development

Following the key propositions presented in their seminal work, Griffin and his collaborators have tested the RISP model in a variety of research contexts. Findings from these studies largely support the relationships depicted in the RISP model, while at the same time, suggest important ways to refine the model.

As the first published empirical piece since the model was introduced, Griffin et al. (2002) drew linkages between the HSM and the TPB, both of which serve as theoretical foundations for the RISP model. Using data from a panel design study conducted in the Great Lakes region, both health risks related to fish consumption and drinking water quality, as well as environmental risks related to the ecosystem of the Great Lakes, were examined. Key findings from this study suggest consistent positive relationships between systematic processing of risk information and TPB measures such as evaluation strength, attitude strength, and the number of strongly held behavioral beliefs associated with environmental hazards. These relationships were also robust because they remained significant under multiple statistical controls. This study is meaningful to the current research project in that it provides initial evidence for the proposed connections between information processing strategies and subsequent attitude formation. In other words, results from this study illustrate Griffin et al.'s (1999) proposition that key components of the RISP model could serve as antecedents to preventive behaviors.

Centering on the key assumption behind the RISP model regarding information insufficiency, Kahlor, Dunwoody, Griffin, Neuwirth, and Giese (2003) explored a novel measure of information processing in a survey setting by sending actual information to participants and then inquiring how they attended to it. Health risks related to the consumption of PCB-contaminated fish in the Great Lakes formed the research context for this study. Results from this study indicated that as the gap between current knowledge and information sufficiency threshold increased, systematic processing of the relevant information also increased. These findings confirmed the value of studying audiences' information need, which could inform message design for risk communication. In the meantime, this study also provided an alternative measurement strategy for key dependent variables of the RISP model such as information processing.

In order to further explore what contributes to the sense of information insufficiency, Griffin, Neuwirth, Dunwoody, and Giese (2004) adopted a more socio-psychological approach to examine the relative impact of affective responses (worry), hazard characteristics (risk judgment, personal control and institutional trust), and informational subjective norms on information insufficiency. Based on the knowledge gap hypothesis, education was also analyzed together with current knowledge, the baseline measure for information insufficiency. This study formalized measures for key components of the RISP model. Key findings indicated that worry and perceived normative pressure could raise one's information thresholds above what they currently knew. However, among the different dimensions of hazard characteristics, only perceived severity was significantly related to information insufficiency, through the intervening variable of worry. Since data collection for this study was carefully constructed to ensure generalizability, the contribution of demographic and other individual characteristics also deserves attention. In particular, minority respondents

reported greater worry associated with the potential risk, as well as sensing more normative pressure to stay on top of risk information. Concurrently, another study focused on the immediate predictors of information seeking and processing in two research contexts involving environmental risks (Griffin, Powell et al., 2004). Except for perceived information gathering capacity, both information insufficiency and relevant channel beliefs were related to information seeking and processing in the hypothesized directions.

The larger research project based on the Great Lakes ecosystem offered data for the four studies discussed above. Moving on to a new domain, Griffin et al. (2005) tested the applicability of the RISP model to communication issues related to energy. Key measures for this study were consistent with previous analyses, even though relevant channel beliefs were mainly assessed based on the usefulness of different channels in providing energy-related information. Energy use is not directly a risk issue, but the communication of energy involves the use of technical terms and has broad societal impact. Therefore, this study attested to the potential of the RISP model in guiding communication studies beyond those directly related to risk. More importantly, this study also reflected an initial effort in analyzing informational subjective norms as a direct, rather than indirect predictor of information seeking and processing. Key results from this study indicated positive relationships between the RISP model's dependent variables and their key predictors: informational subjective norms, information insufficiency, capacity and channel beliefs.

Similar to the energy issue, risks that do not pose direct harm to individuals' well-being but threaten the larger environment present a unique context to evaluate the RISP model. Focusing on risk information related to the environment solely, Kahlor, Dunwoody, Griffin, and Neuwirth (2006) used a section of the RISP model to examine whether it could be applied to this new form of risk, formally termed as impersonal

risk. Findings from this study were consistent with Griffin et al. (2005), disclosing a more complex role that informational subjective norms might play in influencing information seeking and processing when individuals face impersonal risks. Specifically, Kahlor et al. argued that the strong direct relationships between informational subjective norms and information seeking and processing might be a function of impersonal risk because social pressure might seem more salient when direct threat was absent. In the meantime, the link between informational subjective norms and information insufficiency might also indicate a transformation of social norms into personal norms, a new interpretation for a consistent finding based on the RISP model. This study was significant in that it extended the scope condition in which the RISP model functions to impersonal risks. Considering the current research project, since clinical trial opportunities might not represent direct risks to healthy adults in the national sample, the RISP model could be further examined in this domain.

Following the direction of exploring impersonal risk, Kahlor (2007) proposed an augmented version of the RISP model to examine environmental risk information seeking. In this study, TPB measures such as attitude toward the behavior, perceived behavioral control, and behavioral intent, were incorporated into the RISP structure because of their general robustness in predicting behavior. Based on results from structural equation modeling, the proposed model accounted for 72% of the variance in behavioral intention, with all the main hypotheses supported except for those involving perceived behavioral control. This study was unique in that it distinguished intentions for information seeking from actual seeking behavior and offered further evidence for the direct relationship between informational subjective norms and information seeking intentions. With its focus on information seeking as the main dependent variable, this model also informs the current research project because it laid

out alternative means to test the connections between the RISP model and the TPB, different from those employed by Griffin et al. (2002). A caveat here, however, is that the strong impact of informational subjective norms might again be a function of the research context that involves impersonal risks. It would be meaningful to compare whether this component would function in similar manners when both impersonal and personal risks are present. The current research project, with comparable data sets from two different populations, might explore this possibility.

Even though different emotions could function as part of the RISP model to motivate information seeking and higher-level information processing, up until Kahlor (2007), only one specific emotion had been tested - worry. In order to explore other possibilities, Griffin et al. (2008) examined the role of anger in a context of flooding risk management in watershed urban regions. Specifically, this study focused on the amount of anger that watershed residents felt toward watershed managing agencies. Along with this new addition to the affective responses component, this study also investigated the potential role of causal attributions in shaping people's overall risk perception. This study tested the RISP model in its entirety and contributed to theory development in several important aspects. Based on attribution theory (Nisbett, Borgida, Crandall, & Reed, 1976) and appraisal theory (Lazarus, 2006), this analysis confirmed that causal attribution and angry feelings could function together with other RISP components in motivating information seeking and processing. In addition, the direct influence of informational subjective norms on key dependent variables emerged once again. However, channel beliefs remained weaker and somewhat inconsistent predictors of seeking and processing. Griffin et al. concluded that when risks become public issues and not just private concerns, such as those associated with a lack of effective management for flooding risks, the RISP model could help to describe the public's risk communication activities. On a conceptual front end, this

analysis also shows that the RISP model is a work in progress. New dimensions of various components, as well as their measurement strategies, await researchers to continue to explore. The current research project, largely motivated by these possibilities, will test the inclusion of other emotions and, perhaps, a revision of the overall model.

Research that aims at testing alternative formulation of the RISP model have already started. Following the proposition of the augmented RISP model, Kahlor and Rosenthal (2009) studied whether antecedents of information seeking about global warming, as portrayed in the RISP model, could also predict actual knowledge about this topic. This study generated mixed results, showing education, prior seeking effort, and the number of news media sources as most strongly related to actual knowledge. Only instrumental attitudes (related to utility) toward information seeking, however, was positively related to knowledge, whereas attitudes based on experiential evaluations of the behavior were negatively related to knowledge. In contrast, key components of the RISP model such as worry, subjective norms, personal relevance, and perceived behavioral control, were not significantly related to knowledge. Kahlor and Rosenthal offered various explanations for the lack of findings in their study. Overall, they suggested that measures for key variables of the RISP model still need improvement. However, their study showed that past information seeking effort did correlate positively to current knowledge, which supported the underlying notion of the RISP model that communication behaviors such as information seeking and processing could enhance individuals' awareness and comprehension of risk information. Kahlor and Rosenthal also contributed to theory development in that they offered a more detailed account for attitudes as a predicting variable for information seeking. In fact, they continued to argue that attitudes could serve as a more generic measure in replacement of relevant channel beliefs, one of the weakest components of

the RISP model.

The most recent analysis of the RISP model involves a comparison of two independent samples in the United States and the Netherlands on the issue of industrial safety related to the storage and transportation of hazardous substances. In this study, Huurne et al. (forthcoming) tested alternative measures for information insufficiency with multiple Likert-type items. They also tested direct paths from informational subjective norms and affective responses to information seeking, and directly associated current knowledge with perceived information gathering capacity. Overall, their results supported the RISP model's main propositions. In particular, they found that negative emotional reactions were among the strongest predictors of individuals' information seeking behavior. The two samples mainly differed in that informational subjective norms seemed to have a more direct impact on information seeking in the US sample, whereas in the Dutch sample, this variable was indirectly related to information seeking through information insufficiency. In terms of theoretical contribution, their findings justified the proposed modifications to the original RISP model. These authors also encouraged subsequent research to explore whether the model should be similarly modified when employed to study information processing. Backed by evidence from these recent studies, it seems vital to adapt the RISP model to represent these new modifications. If the current research project generates additional evidence in support of these revisions within a context of health communication and health decision making, we should give reformulation of the RISP model its due attention.

Future Directions

Initial empirical tests based on the RISP model formed a theory-driven progression with a clear overarching goal to advance knowledge in this area. Griffin and his collaborators first tested both sides of the model in separate studies, based on

which the whole model was examined in at least four different research contexts. Even though the RISP model was under some criticism for its lack of parsimony, the comprehensiveness of the model allows it to account for many of the key mechanisms that risk communication research has identified to influence communication behaviors over the years. Recent analyses using structural equation modeling, when supported by an adequate sample size, also show evidence that the model fit well to data gathered from different practical domains. Examining the empirical studies reviewed above systematically, the next stage of development for the RISP model could focus on the areas described in the following paragraphs.

First, there should be additional tests of the model in its entirety because different parts of the model have already demonstrated their capacity in portraying individuals' varied motivations for risk information seeking and processing, as depicted in the RISP model. Kahlor (2007) offered practical recommendations for data analysis in this regard, especially when it comes to subjecting certain exogenous variables (such as current knowledge) as controls when evaluating the relative impact of others (for instance, information sufficiency). Alternatively, to avoid ceiling effects, Huurne et al. (forthcoming) tested a different measurement strategy for information insufficiency, which seems more straightforward for a path analyses approach. When resources and logistics allow, future research should probably consider including both to measure this fundamental mechanism of the RISP model - information insufficiency - so that its influence on the dependent variables do not get washed away due to measurement errors. In addition, it has always been a compromise to capture this subtle mental calculation process through self-report questionnaires. Future studies should consider including experimental elements in the research design to evaluate this cognitive need for information more precisely.

Testing the model in its entirety will also allow the relative impact of different

predicting variables to be assessed in the presence of each other, which might present findings that are different from earlier studies. For instance, in several initial studies, based on results from multiple regression analyses, perceived information gathering capacity seemed to have a rather significant impact on information seeking and processing (Griffin, Powell et al., 2004; Kahlor et al., 2003, for instance). In later analyses, especially those using structural equation modeling, this variable seemed less influential as compared to other RISP components (Kahlor, 2007; Huurne et al., forthcoming, for instance). Therefore, at this stage of development for the RISP model, it is essential to test multiple hypotheses at once based on covariance structures while taking into account potential measurement errors.

Second, when limiting the scope to analyze only those studies that focus on key relationships proposed within the RISP model, this review also identified some interesting patterns (Table 2.1). First of all, perceived hazard characteristics were proposed to be a multi-dimensional construct that likely includes risk judgment (probability * severity), perceived behavioral control, institutional trust, and causal attribution. Some of these constructs, however, have consistently shown rather limited impact on the dependent variables. In cases where statistical significance was achieved, the relationships were mostly based on indirect effects that are difficult to interpret with clear conclusions. For instance, Griffin et al. (2008) found that anger towards watershed managing agencies was significantly related to information insufficiency, information seeking, and systematic processing. Various aspects of perceived hazard characteristics, given their significant relationships with anger, therefore, were indirectly related to these dependent variables. As a newly added dimension to perceived hazard characteristics, however, only two out of the five causal attributions were significantly related to anger. In another study that specifically focused on antecedents to information insufficiency, only the estimates of

probability and severity related to the potential risk had significant relationships with worry and information insufficiency, while institutional trust and personal control had marginal relationships with worry, and no significant relationships (direct or indirect) with information insufficiency (Griffin, Neuwirth et al., 2004). Concluding from these observations, even though risk perception is indeed a multiplex concept that calls for comprehensive measures, to assess its impact on communication behaviors such as information seeking and processing, it might be more feasible to keep it simple and easy for operationalization.

Table 2.1
Overview of results from past analyses of the RISP Model

Key Predictors	Information Insufficiency	Information Seeking	Systematic Processing	Heuristic Processing
Perceived Hazard Characteristics				
<i>Probability</i>	b			a
<i>Severity</i>	b			
<i>Personal control</i>				
<i>Institutional Trust</i>				
Affective Responses				
<i>Worry</i>	b f			
<i>Anger</i>	g	g	e g	
<i>Negative emotions</i>	h	h		
Subjective Norms	b c e f g h	d e f g h	d e g	d e g
Current Knowledge	b e f g h	c e f g h	c e	c d e
Sufficiency	--	c d e f g h	a c d e g	c d e g
Channel Beliefs				
<i>Media distort</i>				g
<i>Validity cues</i>		c	c e g	
<i>Usefulness</i>		d	d	d f
Perceived Information Gathering Capacity		c d g h	c g	a c g

Notes:

- a. Kahlor et al. (2003)
- b. Griffin, Neuwirth et al. (2004)
- c. Griffin, Powell et al. (2004)
- d. Griffin et al. (2005)
- e. Kahlor et al. (2006)
- f. Kahlor (2007)
- g. Griffin et al. (2008)
- h. Huurne et al. (forthcoming)

Among the studies that assessed worry, anger, or a latent construct representing different negative emotions such as anxiety and discomfort, consistent findings have supported their motivational effects, directly or indirectly through information insufficiency, on information seeking and systematic processing. Conceding the fact that different specific emotions might differ in the type of action tendencies they engage (Lerner & Keltner, 2001), most negative emotions, when associated with a risk situation, are likely to heighten a cognitive need for more information, albeit for differing goals or reasons (Raghunathan & Pham, 1999). Therefore, within the context of the RISP model, since affective responses are examined along with risk perception and information insufficiency, as a mediating variable between the two, it might be more cost-effective to explore emotions based on the general valence they represent. Realistically, it is almost impossible to capture the delicate difference in functionality among different specific emotions through survey data. Tracing back to the original propositions of the RISP model, however, it might be valuable to compare the relative impact of positive and negative emotions. Generally speaking, negative emotions usually come in tandem with any circumstance that involves risk. However, in situations where the outcome is unclear and uncertainty is high, it might be meaningful to take into consideration the effect of positive emotions, such as hope, that might occur due to one's ambiguous anticipation for future results.

Serving as key motives for information seeking and processing, information insufficiency has functioned consistently throughout these studies. Informational subjective norms, in similar ways, have performed well in hypotheses testing. More importantly, as mentioned earlier, when informational subjective norms are examined as a direct motive for seeking and processing, rather than through information insufficiency, the proportion of variance explained by this component deserves further

recognition. Future analyses could also investigate the relative direct and indirect effects that informational subjective norms exert on key dependent variables, in an attempt to justify a repositioning of this component in the model. As an organic linkage between the RISP model and the TPB, this variable is expected to not only influence communication behaviors but also have some impact on subsequent attitudinal positions and behavioral intentions.

In contrast, relevant channel beliefs have always been a weaker predicting variable, which leaves a lot of room for improvement in the conceptualization and measurement of this component. A closer examination of the different strategies employed so far, however, indicates that validity cues (whether a specific channel offers believable and consistent information) seems slightly better than the other measures for this component. However, research context is expected to determine whether this measurement strategy is appropriate. That is, validity cues would be a sensible measure only when people are already engaged in some sort of information acquisition activities through certain channels. If no such channel is available or accessible, more generic measures for channel beliefs might be necessary. In fact, Kahlor (2007) went as far as to argue that general attitudes toward the targeted behavior could capture the meanings underlying relevant channels beliefs in a replacement of this concept. That is, rather than assessing individuals' beliefs about the quality and ability of specific information channel to supply them with needed information, information seeking, in its most basic form, is not necessarily bound to a particular information channel or information source. Thus, general attitudes might have greater utility when evaluated together with other cognition-based motivations for information seeking and processing. When the RISP model is expanded to study communication activities outside of the mass media environment, this strategy could offer a testable alternative for future studies, especially when the RISP model is linked

together with the TPB.

Third, empirical tests of the RISP model started from a context that involves both health risks and ecological risks, then moved on to include issues with broader societal impact such as watershed management, energy, and workplace safety. Kahlor et al.'s (2006) theorization about impersonal risks introduced new domains in which the RISP model could be applied to tackle novel challenges. In particular, as Kahlor et al. (2006) discussed, personal relevancy at times determines people's participation in communication activities and decision making related to risk issues. When the goal of communication is to promote a behavior that does not directly affect personal safety and well-being, however, the RISP model might also be useful to identify more profound value and belief system that people might hold. For instance, in both Kahlor et al. (2006) and Kahlor (2007), normative beliefs were found to have significant direct effects on seeking and processing, as well as indirect effects through information insufficiency. These authors suggested that the contexts of these two studies, having to do with environmental risks that could endanger the greater ecosystem, probably granted this component its unique impact. Taking this conjecture one step ahead, what if the type of risk being examined is even further removed from personal well-being? Would normative beliefs continue to play such an important role? In other words, even though environmental risks are impersonal in nature, they could still influence one's overall well-being. In contrast, what if the potential risk has more to do with other people and does not have any consequence upon oneself? Would these relationships still hold? On a flip side, if the only benefit from engaging in a behavior comes from altruism-based contentment, would the motives described in the RISP model still lead to information seeking and processing?

These questions, while waiting to be tested empirically, also raise other related issues. The RISP model, as well as several other information seeking models, albeit

taking an audience-based approach, often describe the general public as a whole. However, to design effective communication messages, it is of crucial importance to examine specific audience groups, as one of the many publics, to create targeted information campaigns. More importantly, it is insufficient to categorize these audience groups merely based on their demographic characteristics. If the targeted audience group has some form of common experience or history that is not shared by the larger general public, it is likely that communication researchers and practitioners would need to consider the unique features of this group to better suit their need. The current research project, supported by two datasets from a national sample and a patient sample, will offer some insight in this regard. Likewise, the scope of the current research project also presents an opportunity to assess the utility of the RISP model both in an interpersonal setting of doctor-patient communication, as well as in a context where mediated communication occurs, through both traditional media and new media such as the internet.

Lastly, recent theoretical extensions have effectively linked the RISP model back to its theoretical roots and identified new possibilities to enhance the model. On one hand, these extensions reflect other motives for systematic processing as discussed by the HSM. On the other, new ways to conceptualize RISP components as antecedents to the TPB have been proposed and tested. Additional efforts to look at how communication activities might translate into actual behaviors will complement the continuous development of the RISP model. In relation to risk and health communication research on a broader scale, a better understanding of this process is likely to benefit communication scholars and practitioners over time.

Conclusion

As Griffin and his collaborators acknowledged, the RISP model is still a work in progress. An increasing amount of evidence has shown that a cognitive need for

more information is not necessarily the only, or even the most important, factor to motivate risk information seeking and processing. Emotions, normative beliefs, and general attitudes might exert stronger influences on seeking and processing in certain settings. In other words, research context plays an important role in delineating how various parts of the model work together to shape communication behaviors. Even though the RISP model was constructed based on social psychology theories, to solve practical problems with broad societal impact, communication scholars have managed to study various complex psychological processes in field settings. This project, informed by past and ongoing research based on the RISP model, will strive to respond to the issues reflected above. Testing the applicability and extension of the RISP model in this context of health decision making related to clinical trial enrollment also offers a range of possibilities for comparative investigations.

Method Overview

Survey Research

The current project was supported by a research grant from the Leukemia & Lymphoma Society (LLS). Before data collection, Institutional Review Board (IRB) approval for social and behavioral studies involving human participants was sought and granted. A copy of the IRB application form is attached in Appendix 1.

For comparison purposes, two telephone surveys were conducted that repeated the same questions when applicable to the sampled population. Since clinical trial participation, in general, is more relevant to the LLS sample, how their responses are similar to or different from the national sample might offer useful information to improve communication about clinical trial enrollment. In total, 1,000 interviews were completed. Reproductions of the questionnaires appear in Appendix 2A and 2B.

Using a random digit dial (RDD) sample of the general population purchased from a professional sampling firm, Cornell University's Survey Research Institute

completed 500 interviews for the national sample. Data collection began on September 27, 2007 and was completed on October 31, 2007. The response rate was 24% and the cooperation rate was 54%, using American Association of Public Opinion Research (AAPOR) calculation standards.

Another 500 interviews were completed for the LLS sample. Respondents were initially contacted by LLS, expressed an interest in the survey, and were interviewed in a follow-up phone call. Data collection began on October 5, 2007 and was completed on October 28, 2007. For the LLS sample, the response rate was 67% and the cooperation rate was 99%.

Comparing the demographics of the national sample with those of the LLS sample, respondents in the LLS sample appeared to be older, with higher education. The LLS sample also included more female respondents and more white respondents. The household income for the LLS sample was also slightly higher than that for the national sample.

Of the 491 LLS respondents who categorized themselves, 83.7% were self-identified as patients with cancer diagnosis, 11.6% as caregivers of someone with cancer, and 4.7% as both. Testing for potential differences in responses from these three groups, cancer patients were more likely to express positive attitudes about clinical trials than caregivers. Cancer patients also reported greater trust in their doctors and cared more about their doctors' opinions. Caregivers, on the other hand, were less likely to have previously enrolled in a clinical trial. Those who identified themselves as both cancer patients and caregivers reported slightly more optimism as compared to caregivers, as well as greater attention paid to clinical trial information from medical experts. However, these three groups did not differ significantly in their responses to most key variables of the RISP model. Since cancer patients were the majority group, the LLS sample was treated as a whole in subsequent chapters as

representing a patient sample, except for in Chapter 4, where only cancer patients were included in the analysis.

In general, LLS respondents were more likely to have heard about clinical trial opportunities and enrolled in a clinical trial (about 39% had participated in a clinical trial before the survey). Among key RISP variables, there was significant difference between the national and LLS respondents in terms of knowledge and information sufficiency. LLS respondents were more likely to believe they already know a lot and have sufficient information about enrolling in clinical trials. Respondents from both samples reported similar levels of perceived information gathering capacity. Overall, LLS respondents trusted their doctors more and held more positive beliefs about clinical trial enrollment than respondents in the national sample. They also perceived less risk in clinical trial participation in general, and viewed any degree of potential risk as worth the effort. In contrast, LLS respondents reported greater optimism and anxiety than national respondents when thinking about clinical trial enrollment. LLS respondents generally reported paying more attention to information about clinical trial enrollment.

Up until now, few theory-based studies have examined clinical trial enrollment as a unique communication problem, whereas research from other disciplines have identified a lack of effective communication as posing barriers for patients to make informed health decisions and for medical researchers to advance scientific knowledge. To bridge this gap, guided by the RISP model, this project will integrate health communication and risk communication theories to address these issues:

- To describe the actual information seeking behaviors among healthy respondents, in comparison to those among cancer patients and their caregivers. This comparison will primarily focus on whether cancer patients and their caregivers, as a specific audience group, engage in routine and non-routine information seeking for

similar reasons as respondents in the national sample (Chapter 3).

- To explore whether positive emotions could function as part of the affective responses component in the RISP model. This investigation will expand to include a comparative analysis of both negative emotions and positive emotions as they co-exist as motives for risk information seeking and processing and, possibly, as motives for behavioral intentions related to clinical trial enrollment (Chapters 3, 5, & 6).
- To assess structural models with direct paths from informational subjective norms to information seeking and processing and those with information insufficiency as a mediating variable. Model fit indices will offer some insight as to whether informational subjective norms work better serving as a primary indicator for seeking and processing along with information insufficiency (Chapters 4 & 6).
- To investigate the impact of outcome variables of the RISP model, systematic processing and heuristic processing, on cancer patients' attitudes and behavioral intentions related to clinical trial enrollment. Findings from this analysis will offer evidence-based recommendations to improve health campaigns that aim to facilitate informed decision making among cancer patients (Chapter 5).
- To test a new measurement strategy for relevant channel beliefs. Since most communications about clinical trials happen between doctors and patients, general trust in doctors seems a reasonable way to measure whether respondents believe that they are provided with unbiased and useful information (Chapters 4 & 5).
- To compare data from the two samples when RISP components are treated as antecedents to the TPB. The goal of this analysis is to generate more conclusive findings, based on multiple-sample structural equation modeling, about what factors might drive respondents in these two samples to enroll in a future trial. Results from this comparative investigation will bear important practical implications (Chapter 6).

The following chapters reflect these attempts.

CHAPTER 3

INFORMATION SEEKING RELATED TO CLINICAL TRIAL ENROLLMENT¹

Information seeking has been a central topic in communication research as it provides organic linkages between message senders' intentions and receivers' needs. In recent years, communication scholars have proposed a variety of theoretical models to document the antecedents and outcomes of information seeking in different research contexts, especially those such as health communication that target audiences' attitude formation and behavior changes (Afifi & Weiner, 2004; Case, 2002; Griffin et al., 1999; Johnson, 1997). In the meantime, the audience-oriented approach, as part of the health communication research tradition, determines that an increasing amount of scholarly works is attending to how members of the public incorporate mediated health messages in their personal health decisions (Johnson & Meishcke, 1992; Niederdeppe, Frosch, & Hornik, 2008). Recent theoretical development, in particular, has argued for a distinction between active, purposeful information seeking and casual, incidental exposure to information.

In particular, communication researchers have acknowledged that in an information-saturated media environment, health information is broadly available, even if not always strategically planned or readily accessible (Brashers et al., 2002; Niederdeppe et al., 2007; Romantan, Hornik, Price, Cappella, & Viswanath, 2008). According to these authors, health communication has entered a consumer paradigm in which individuals could pick and choose among various information channels to acquire the most relevant and useful information to assist with their health-related decision making (Cassileth, Zupkis, Sutton-Smith, & March, 1980; Fallowfield, Ford, & Lewis, 1995; Sharf & Street, 1997). For instance, past research has found that even

¹ A version of this chapter has been accepted for presentation to the Mass Communication & Society Division of the Association for Education in Journalism and Mass Communication Annual Convention in Boston, MA, August 2009.

though purposive information seeking behavior occurs less frequently and involves fewer sources than other routine patterns of information acquisition, termed as information scanning, targeted information seeking exerts greater influence on health-related decisions (Niederdeppe et al., 2007).

Specifically related to clinical trial enrollment, even though doctor-patient communication plays an important mediating role in influencing patients' decisions about participation (Albrecht et al., 2003), research suggests that a large percentage of potentially eligible patients are not offered trials during interactions with their doctors (Albrecht et al., 2008). Other researchers have described physicians' lack of communication about clinical trial opportunities as "the greatest source of lost opportunities" (Siminoff & Thomas, 2008, p. 2614). If we consider potential trial participants as consumers of health information, then we should also consider that those patients' information needs and information seeking behaviors might influence the nature of communication that takes place with their doctors. As Leydon et al. (2008) pointed out, even though all patients want basic information on diagnosis and treatment, their attitudes and strategies for coping with illnesses can constrain their wish for information and their efforts to obtain it.

Recent research has identified that the media continue to function as a powerful information source and motivator for prospective clinical trial participants. For instance, a recent study found that while media coverage about clinical trials spurred prospective participants to contact their physicians for further discussion, it did not inflate unrealistic hope or cause misunderstanding among these individuals (Pentz et al., 2002). Therefore, it seems important to further examine individuals' seeking of information related to clinical trial enrollment, especially given evidence showing that many patients begin to make decisions about entering a trial prior to any formal discussion with their doctors or other clinical investigators (Gordon &

Daugherty, 2001). More importantly, similar to other health-related issues, we should focus this investigation on factors that might motivate individuals to go beyond what is offered in the traditional media to explore what is available through alternative channels. For example, recent research has identified that the internet could serve as an effective means to acquire health information, especially when the goal of information seeking is to obtain greater knowledge (James et al., 2007; Lemire, Paré, Sicotte, & Harvey, 2008). At the same time, most clinical trial search tools on the internet require that users be fairly knowledgeable about their medical condition and sophisticated in their web navigation skills (Atkinson et al., 2008). That is to say, greater motivation seems a contingency behind these non-routine information seeking activities.

To investigate the individual and social factors that work together to motivate information seeking about clinical trial enrollment, this chapter employs a derivative of the Risk Information Seeking & Processing (RISP) model (Griffin, Dunwoody, & Neuwirth, 1999), the Augmented Risk Information Seeking (ARIS) model (Kahlor, 2007). In this analysis, clinical trial enrollment is viewed as a unique case study for risk because potential risks involved in the trial procedure (e.g., fear of randomization, side-effects) pose barriers for many prospective participants (Avis et al., 2006; Jones et al., 2006; Linden et al., 2007; Stryker et al., 2006). The comparisons between data from the national sample and the LLS sample will help to draw evidence-based recommendations on how to improve the communications of clinical trial enrollment.

Augmented Risk Information Seeking Model

Based on empirical evidence that has accumulated over the past decade, Kahlor (2007) proposed the ARIS model and tested it in the context of risk information seeking related to global warming (Figure 3.1).

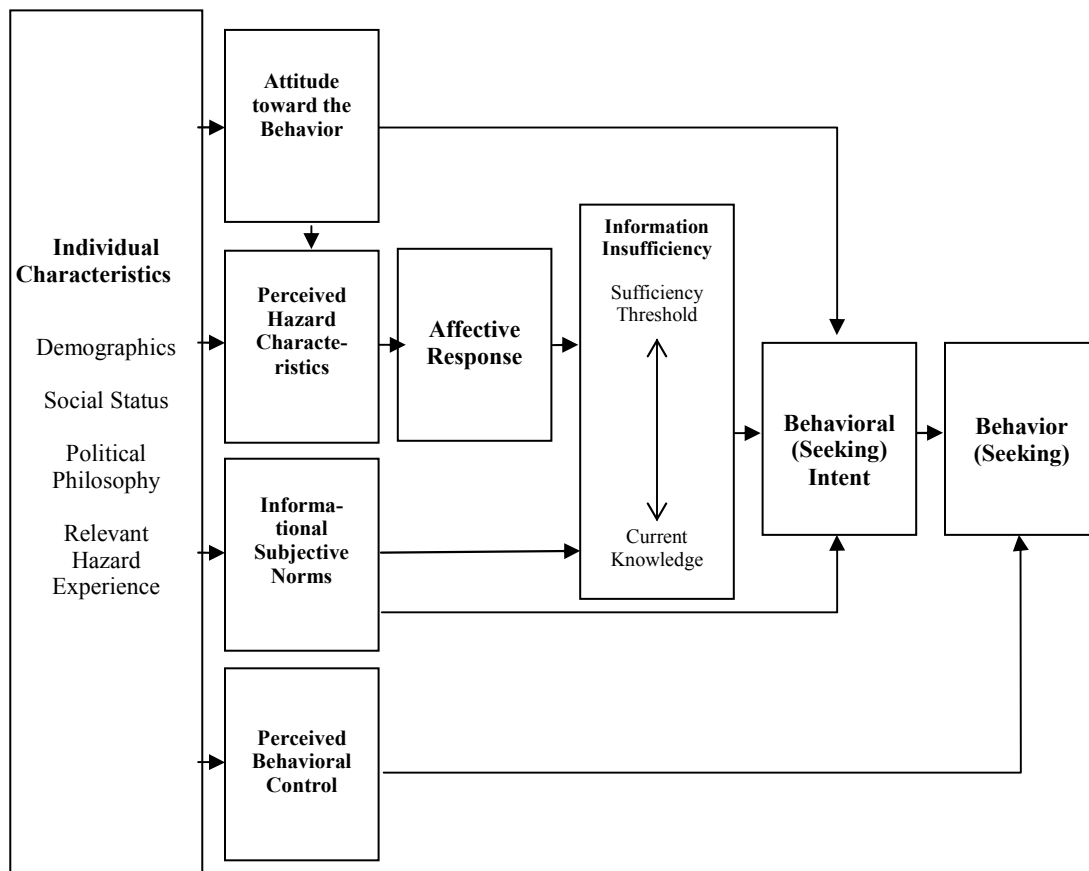


Figure 3.1
Augmented Model of Risk Information Seeking (adapted from Kahlor, 2007)

Similar to the RISP model, the ARIS model suggests that the motives for seeking judgmental confidence are based on validity and the motives for holding and maintaining socially acceptable attitudes drive information seeking behaviors, as posited by the HSM. In addition, the ARIS model incorporated an additional TPB concept, belief-based attitudes, which along with subjective norms and perceived behavioral control already constitute the RISP model. According to Kahlor, this integration would “enable researchers from different disciplines to recognize they are pursuing similar phenomena” (p. 419). Since this chapter primarily focuses on information seeking, I will apply the ARIS model to test its applicability to a health-related communication issue. In addition to the relationships that the ARIS model

depicts, since the present analysis does not submit to the same technical constraint for latent-variable models (Kahlor, 2007), I will also examine the influence of individual characteristics at the background of the original RISP model. Specifically related to clinical trial enrollment, key components of the ARIS model include:

Information insufficiency. Based on HSM's assumption of validity-seeking motives, this concept describes how the need to achieve information sufficiency could influence the extent to which individuals seek out risk information in both routine and non-routine channels.

Perceived hazard characteristics. Consistent with the original RISP model, cognitive evaluations of a potential risk, defined through a multidimensional construct that includes risk judgment, institutional trust, personal control, and causal attribution, could contribute to one's sense of information insufficiency and indirectly influence information seeking.

Affective responses. Recent development of the RISP model has identified indirect and direct relationships between affective responses and information seeking (Griffin et al., 2008; Kahlor, 2007). However, very few studies have compared the relative impacts of negative and positive emotions. With the exception of optimistic feelings, most existing literature has only identified negative emotions, such as fear, worry, and anxiety, as having an impact on individuals' decisions to participate in a clinical trial (Madsen et al., 2002; Meropol et al., 2007; Schain, 1994). These negative and positive emotions are expected to influence information seeking in similar ways, but for different reasons. Specifically, even though negative emotions are likely to highlight a need for greater attention to specific risk information (Bless & Schwarz, 1999), positive emotions could also enhance individuals' interest in potentially negative information (Aspinwall & Brunhart, 1996; Trope & Neter, 1994).

Informational subjective norms. Besides seeking validity and information

sufficiency to achieve judgmental confidence, the desire to defend one's existing opinions and the desire to form socially acceptable attitudes could also motivate greater attention to information (Chaiken et al., 1989; Eagly & Chaiken, 1993). The ARIS model incorporates these alternative motives through the informational subjective norms component, which suggests that individuals' information seeking may be motivated by their willingness to fulfill others' expectations about their information level. Recent studies have presented evidence in support of this proposition (Griffin et al., 2008; Kahlor, 2007; Kahlor et al., 2006).

Behavioral control (perceived information gathering capacity). In addition to motivation, capacity also plays an important role in dual-process theories such as the HSM. Integrating with TPB's behavioral control concept, the ARIS model suggests that individuals' perceived information gathering capacity (self-efficacy and controllability of the behavior) is likely to influence information seeking.

Attitude toward the behavior (seeking). The ARIS model adapted the relevant channel beliefs component of the original RISP model to include attitudes toward the behavior. As Kahlor (2007) argues, this reconceptualization represents a paradigmatic shift away from specific channels to a more holistic and general manner (also reflected in Case, 2002).

Behavioral intent (seeking). Consistent with the TPB, this concept describes individuals' general intention to seek information.

Behavior (seeking). Griffin et al. (1999) suggests that besides habitual information gathering, the sufficiency principle can also motivate non-routine seeking of information, which involves "active attempts to gather relevant risk information that go beyond routine sources" (p. S238). No empirical work to date has distinguished these two types of information seeking within this theoretical framework; this analysis, therefore, represents a first attempt to evaluate this

proposition in the formulation of the ARIS model.

Research Questions and Hypotheses

The main objective of this chapter is to examine whether the ARIS model explains motivations for the seeking of information about clinical trial enrollment through routine and non-routine channels in two comparable samples. Even though no previous research has compared the model components' relative influences on routine and non-routine information seeking, based on existing evidence (Griffin et al., 2008; Kahlor, 2007; Kahlor et al., 2006), several hypotheses were proposed:

Table 3.1
Hypothesized relationships between routine/non-routine information seeking and components of the Augmented Risk Information Seeking and Processing Model

	Routine Information Seeking	Non-routine Information Seeking
Information insufficiency	H1a (+)	H1b (+)
Risk Judgment	H2a (+)	H2b (+)
Affective responses	H3a (+)	H3b (+)
Informational subjective norms	H4a (+)	H4b (+)
Behavioral control	H5a (+)	H5b (+)
Attitudes toward the behavior	H6a (+)	H6b (+)
Behavioral intent	H7a (+)	H7b (+)

This chapter also examines the relationships between the dependent variables and individual characteristics including demographic variables:

RQ1: Do individual characteristics influence routine/non-routine information seeking?

To compare information seeking behaviors among healthy respondents and members of a patient advocacy group, the next research question is:

RQ2: Does group membership moderate the relationships between ARIS variables and the dependent variables, routine and non-routine information seeking?

Method

Data

To examine specific hypotheses, data from the national sample and the LLS sample were first pooled together to describe general information seeking patterns among the respondents. In order to investigate differences between these two samples, interaction terms involving group membership and other key variables were constructed. Since 82.2% of the respondents in the LLS sample were cancer patients, with an additional 4.6% of them being both cancer patients and caregivers, this group was treated as a patient sample.

Measurement

Measures for key variables were adopted from past analyses based on the RISP model (Griffin et al., 2008; Griffin et al., 2002). Specific measures are shown in Appendix 2A and 2B.

Information insufficiency. On scales from zero to 100, information insufficiency was measured with two variables that asked respondents to assess how much they knew about clinical trial enrollment ($M = 38.49$, $SD = 32.33$) and how much they needed to know ($M = 83.41$, $SD = 21.50$) to fully understand this issue (information sufficiency threshold). Consistent with past analyses based on the RISP model (Griffin et al., 2008; Griffin et al., 2004), this analysis did not use the calculated difference in absolute values between these two items to create an “information insufficiency” measure but controlled for current knowledge first in the regression models. As Kahlor (2007) advised in her analysis, this technique helps avoid potential reliability issues and the influence of ceiling effects.

Perceived hazard characteristics: Risk judgment. Given the degree of complexity in the potential risks involved in clinical trials, this analysis used the most generic, and arguably, most frequently used measure, risk judgment, to assess this component (Gregory & Mendelsohn, 1993; Slovic, 1992). On scales from zero to 100, risk judgment was measured based on respondents’ perceived susceptibility to ($M =$

49.15, $SD = 25.65$) and severity of ($M = 51.43$, $SD = 26.77$) of the potential harm involved in clinical trials. The risk judgment scale (susceptibility by severity) based on raw scores was skewed (skewness = 1.17, kurtosis = 1.18), so square root transformation was conducted to create a new scale for further analysis ($M = 48.01$, $SD = 24.54$, skewness = -.13, kurtosis = -.25).

Affective responses. Respondents were asked to indicate on 10-point scales how optimistic, afraid, worried, and anxious they felt when thinking about enrolling in a clinical trial. These three items were condensed them to create a negative affect scale ($M = 16.47$, $SD = 8.36$, $\alpha = .91$). The summed scale was not significantly correlated with optimistic feelings ($M = 5.93$, $SD = 2.60$).

Informational subjective norms. Two items were used to measure whether respondents sensed normative influence from their doctors, friends, family and other people who are important to them ($r = .21$, $p < .001$, $\alpha = .34$).² These two items were summed to create a norm scale ($M = 7.67$, $SD = 1.38$).

Behavioral control (perceived information gathering capacity). To assess this construct, respondents' perceived ability to locate relevant information, as well as their perceived efficacy to comprehend this information ($r = .24$, $p < .001$, $\alpha = .38$) were assessed.³ These two items were then summed to create a behavioral control scale ($M = 6.67$, $SD = 1.70$).

Belief-based attitudes. Respondents indicated their level of agreement with five statements ranging from financial concerns to altruistic reasons related to clinical trials. These statements were adapted from past studies that have identified them as among the most salient beliefs associated with clinical trial enrollment (Comis et al.,

² Items 40 & 41 in the questionnaire

³ Items 23 & 24 in the questionnaire

2003; Schain, 1994). Belief-based attitudes were then linked to their corresponding evaluations and condensed them into a single scale, with higher scores indicating more positive attitudes toward clinical trial participation ($M = 72.54$, $SD = 18.49$, $\alpha = .78$).

Behavioral intent (seeking). Intent for information seeking was assessed with two previously tested items ($r = .37$, $p < .001$, $\alpha = .54$, condensed scale: $M = 7.38$, $SD = 1.90$).⁴

Behavior (seeking). With cross-sectional survey data, this analysis could not precisely assess actual behavior. However, since it is important to distinguish this concept from behavioral intent, respondents' self-reported attention paid to information about clinical trial enrollment was used as a proxy measure for past behavior. In particular, four items inquired about the amount of attention that respondents have paid to routine channels (newspapers and radio or television, $r = .84$, $p < .001$, $\alpha = .91$, $M = 7.59$, $SD = 5.23$) and non-routine channels (websites and internet support groups, $r = .73$, $p < .001$, $\alpha = .84$, $M = 10.46$, $SD = 5.35$).

For the pooled sample, this chapter examined demographic variables including age ($M = 51.93$, $SD = 14.29$, ranging from 18 to 90), gender (54.8% female), race (87.7% White), education from 1 = eighth grade or less to 7 = post-graduate training ($M = 5.25$, $SD = 1.58$), with the largest group being those with post-graduate training, and household income from less than \$10,000 to \$150,000 or more ($M = \$56,700$, $SD = \$22,820$). Other individual characteristics included: (a) awareness of clinical trial opportunities measured from 0 = never heard about opportunities to 4 = heard a great deal ($M = 2.00$, $SD = 1.30$); (b) prior experience with clinical trials (23.5% have enrolled before); (c) visits to doctors in the past 12 months ($M = 24.83$, $SD = 43.66$, ranging from zero visit to daily visits); and (d) likelihood to enroll even if unsupported

⁴ Items 15 & 17 in the questionnaire

by their doctors measured from 1 = strongly disagree to 5 = strongly agree ($M = 3.04$, $SD = 1.16$).

Analysis

This analysis used hierarchical ordinary least squares (OLS) regression to test key hypotheses and examine research questions. Hierarchical OLS allowed these variables to be entered in a series of blocks with the results at each step indicating the relative influence of the variables on the dependent variable while controlling for variables entered in previous steps (Cohen, Cohen, West, & Aiken, 2003). Variables in each block were entered together. Since the condensed sample size was fairly large, this analysis used list-wise deletion to retain only cases with no missing data for key variables.

To test hypotheses, control variables were entered in the first block, followed by ARIS components in subsequent blocks. To answer research questions centered on potential differences between the national sample and LLS sample's information seeking behaviors, I tested interactions between the dichotomous variable of group (National = 0, LLS = 1) and key ARIS variables.

Results

Hypotheses were proposed based on theoretical propositions and empirical evidence showing positive relationships between various ARIS components and information seeking. Results from this analysis, however, provided limited support for these hypotheses (Table 3.2).

The first hypothesis stated that information insufficiency would be positively related to routine and non-routine information seeking. Results from neither regression model supported H1. Information insufficiency did not significantly relate to either type of information seeking.

Table 3.2
OLS regression analysis for routine and non-routine information seeking
(Standardized regression coefficients (betas) except where indicated)

	Routine Seeking	Non-routine Seeking
Sample	-.03	-.18***
Individual characteristics		
Age	-.05	-.05
White	-.12***	-.07
Male	.02	-.03
Income	-.10*	-.03
Education	-.03	-.02
Awareness	.03	.13**
Prior experience	-.00	-.03
Visits to a doctor	-.03	-.03
Ever diagnosed with illness	-.08	-.09*
Would enroll despite doctor	.08*	.09*
ARIS components		
Current knowledge	.04	.05
Risk Judgment	.11**	.02
Optimistic Feelings	.17***	.09*
Negative Affects	.05	.08*
Sufficiency threshold	-.04	-.01
Informational Subjective Norms	.15***	.12***
Information Gathering Capacity	-.03	-.02
Attitudes toward the behavior	.04	.10*
Seeking intent	.13**	.15***
Multiple R	.39***	.46***
Adjusted R ²	.13	.19
ANOVA	F _{20,737} = 6.43	F _{20,731} = 9.61

*Significance regression coefficients are in bold: * $p \leq .05$; ** $p \leq .01$; *** $p \leq .001$.

H2 predicted that risk judgment would be positively related to routine and non-routine information seeking. Results indicated that risk judgment was significantly related to routine information seeking ($\beta = .11, p < .01$), supporting H2a, which indicated that those who perceived greater risk in clinical trials were also more likely to pay attention to relevant information through routine channels. However, H2b was not supported. The relationship between risk judgment and non-routine information seeking was not significant.

H3 suggested that both positive and negative emotions would be positively related to routine and non-routine information seeking. Results from this chapter suggested partial support for this hypothesis. Specifically, positive affect (feeling optimistic when thinking about clinical trial enrollment) significantly related to both routine ($\beta = .11, p < .01$) and non-routine information seeking ($\beta = .09, p < .05$). Negative affects (fear, worry, anxiety) were significantly related to non-routine information seeking but not to routine information seeking.

H4 indicated that informational subjective norms would be positively related to both routine and non-routine information seeking. Results from this analysis provided strong support for this hypothesis. Respondents who cared about the opinions of their doctors, family members and friends also were more likely to engage in both forms of information seeking.

H5 stated that behavioral control (perceived information gathering capacity) would be positively related to routine and non-routine information seeking. This hypothesis did not receive any support in the data.

H6 suggested that positive attitudes toward clinical trials would be positively related to routine and non-routine information seeking. Statistical findings indicated no significant relationship between positive attitudes and routine information seeking and a marginal significant relationship between positive attitudes and non-routine

information seeking ($\beta = .10, p < .05$). Positive attitudes toward clinical trial participation seemed to drive the respondents to seek information actively through non-routine channels but not necessarily motivate them to pay more attention to this information in the traditional media.

The last hypothesis focused on the relationship between general intent for information seeking and specific information seeking behaviors. Data from both regression models provided support for H7: Those who reported stronger intention to seek information about clinical trials also seemed to have paid more attention to relevant information through both routine and non-routine channels.

With regard to the first research question, the results found that among the demographic variables and individual characteristics, white respondents were less likely to engage in routine information seeking as compared to minority respondents ($\beta = -.12, p = .001$). Respondents with higher income were also less likely to seek information through routine channels ($\beta = -.10, p < .05$). However, none of the demographic variables was significantly related to non-routine information seeking. Both awareness ($\beta = .13, p < .01$) and illness diagnosis ($\beta = -.09, p < .05$) were significantly related to non-routine information seeking, but neither related to routine information seeking. In contrast, those who reported that they would enroll in clinical trials even without their doctors' support were more likely to engage in both types of information seeking.

To answer the second research question, further analysis tested interactions between the sample and key ARIS variables. Group membership seemed to moderate the relationships between non-routine information seeking and three ARIS variables: risk judgment, negative affect, and informational subjective norms. Specifically, when data from the two samples were examined together, the effects of risk judgment on non-routine information seeking in both samples seemed to have canceled each other

out, which generated non-significant results in the regression model. The significant interaction (sample * risk judgment, $\beta = .12, p = .01$), however, suggested a different story. To gain a better understanding of the relationships between these variables, hierarchical regression model parameter estimates were used to graph non-routine information seeking by risk judgment and sample membership (Figure 3.2). There was a positive relationship between risk judgment and non-routine information seeking among LLS respondents and a seemingly equally strong negative relationship between risk judgment and non-routine information seeking in the national sample.

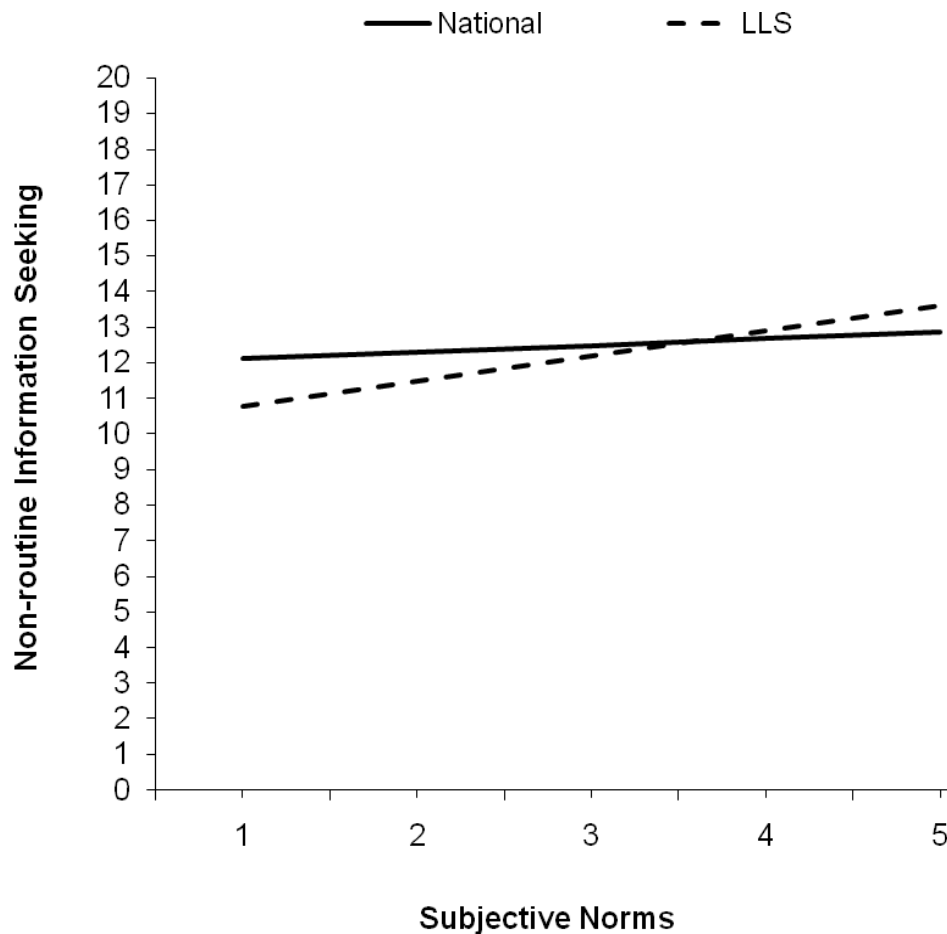


Figure 3.2
Model predicted relationship between non-routine information seeking and information subjective norms by sample ($n = 751$)

In contrast, the positive relationship between negative affects and non-routine information seeking in the whole sample seemed driven mainly by responses from the LLS sample (sample * negative affects, $\beta = .15$, $p = .001$). As shown in Figure 3.3, the model predicted non-routine information seeking to increase with greater negative emotions among cancer patients and their caregivers, but the relationship between non-routine information seeking and negative emotions was rather flat in the national sample.

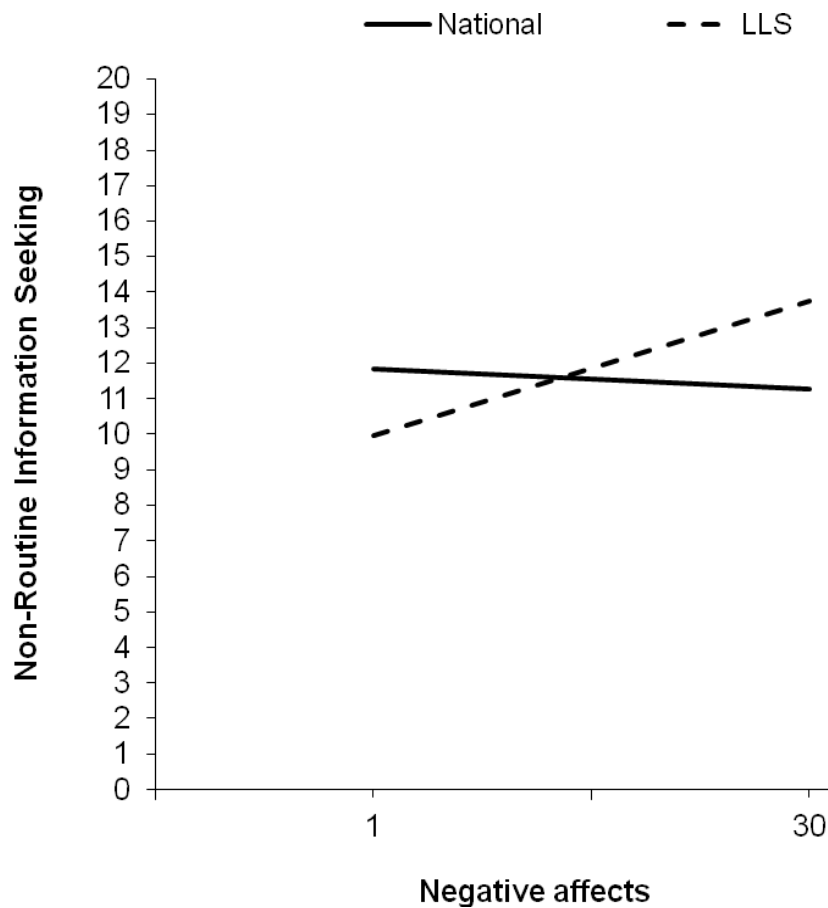


Figure 3.3
Model predicted relationship between non-routine information seeking and negative affects by sample (n = 751)

As for subjective norms, both relationships were in the positive direction (Figure 3.4), even though the relationship was stronger among the LLS respondents,

with a marginally significant interaction (sample * subjective norms, $\beta = .10, p < .05$).

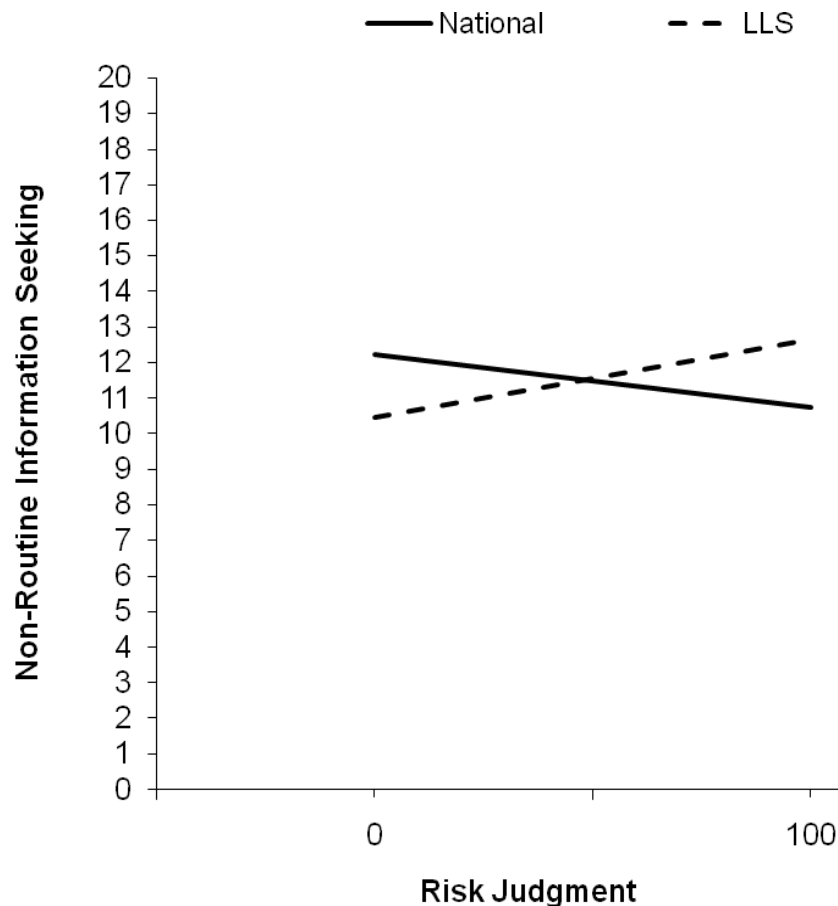


Figure 3.4
Model predicted relationship between non-routine information seeking and risk judgment by sample (n = 751)

Discussion

This chapter provides some evidence in support of the ARIS model and its predecessor, the RISP model. When comparing responses from a national sample of mainly healthy participants and a sample of cancer patients and their caregivers, some interesting differences between these two samples emerged with regard to the relative impact of various ARIS components on routine and non-routine information seeking. Informing theory development, these results highlight the importance of distinguishing purposive, targeted information seeking through non-routine channels from the more

casual, generic form of exposure to information through routine channels. These findings also suggest important practical implications in relation to designing health communication campaigns that aim at enhancing awareness and understanding of clinical trial enrollment among the general public.

Viewing these results as a whole, cognitive evaluation of and affective responses to potential risks involved in clinical trials seem to motivate both routine and non-routine information seeking. In particular, respondents who reported feeling more optimistic when thinking about clinical trial enrollment in both samples also reported greater information seeking in general. However, negative emotions associated with clinical trials mainly motivated non-routine information seeking, which potentially requires more time and effort. These findings support the reasoning that even though positive and negative emotions might function in similar ways in motivating information seeking, different psychological mechanism might be at work. Sample membership also moderated the relationship between negative affects and non-routine information seeking, as well as the relationship between risk judgment and non-routine information seeking. That is, cancer patients and their caregivers who sensed greater risk and associated more negative emotions with clinical trial enrollment were also more likely to spend time searching for information about clinical trials online through health websites and internet support groups. Therefore, even though optimistic feelings might increase curiosity and interest in general information related to clinical trials among these respondents, risk judgment and negative feelings seem to play more significant roles in driving them to active information seeking, especially among those for whom this issue bears greater relevancy.

Subjective norms and intentions for information seeking also performed consistently in their effects on routine and non-routine information seeking. These

results provide support for the relationships outlined in both the TPB and ARIS model. Respondents who acknowledged greater social influences from their doctors and other important people in their personal network such as family and friends were also more likely to pay attention to information about clinical trial enrollment through both routine and non-routine sources. However, the impact of social norms was slightly stronger among the LLS respondents, for whom the decision to participate in a clinical trial might represent a practical issue in their interactions with these important people in their social network. The positive relationships between behavioral intent and past behavior seem to have supported the decision to operationalize these constructs in this manner.

Surprisingly, information insufficiency and behavioral control failed to show any significant relationship with the dependent variables. In light of these results, it seems that the need for validity-based information sufficiency may not serve as the primary motivator for information seeking in this research context. As Griffin et al. (2008) pointed out, it is possible that affective responses and informational subjective norms could at times work independently of information insufficiency, a cognitively based motivator. Results from this analysis seem to reflect this notion. The information seeking activities included in this chapter involved getting information from traditional media or the internet. In this day and age, none of these activities is likely to require an effort that is much beyond the information gathering capacity of the respondents, who had an average education level in the range of post-graduate training. Therefore, the amount of variation in behavioral control (and education, for that matter) did not account for the differences in information seeking activities. To better assess behavioral control in this context, future research might need to emphasize more an individual's ability to comprehend and integrate information that is uniquely related to the specific issue, such as medical information related to the

clinical trial procedure.

Similarly, even though respondents with more positive attitudes toward clinical trials were more likely to seek information through non-routine channels, this positive relationship was only marginally significant. The behavioral beliefs included in the questionnaire were directly related to clinical trial enrollment, rather than the seeking of information related to clinical trials. This might explain why these indirect attitude measures did not perform well as part of the ARIS model. On a conceptual end, as Griffin et al. (2008) stated, future research should continue to examine the reconceptualization of this channel belief component. Compared to the findings reported in Kahlor (2007), nonetheless, it seems that when the behavioral outcome is somewhat foreseeable, such as in the case of global warming, outcome beliefs could supply a meaningful replacement for the original channel belief measures. When the research context involves behaviors with rather unpredictable outcomes such as enrolling in a clinical trial, using outcome beliefs to assess relevant channel beliefs might be less suitable.

Among variables that assessed individual characteristics, minority respondents and those with lower household income were more likely to engage in routine information seeking as compared to white respondents. It is possible that these measures, which are related to people's overall social economic status, also reflect lower accessibility to information on the internet among certain demographic groups. In comparison, respondents who have heard a lot about clinical trials were more likely to search online for related information. Those who expressed a willingness to enroll in a clinical trial against their doctors' recommendations also paid more attention to relevant information from both types of channels. Together, these findings seem to suggest that issue salience still plays an important role in people's decisions to seek information. Respondents who were diagnosed with a chronic or acute illness were

less likely to engage in non-routine information seeking, but the effect was rather minimal.

Study Limitations

Among the independent variables, several condensed scales, such as behavioral control, have achieved limited reliability, which might have contributed to the lack of support for hypotheses that involved this variable. The length of the questionnaire only allowed space for one item to measure optimistic feelings associated with clinical trials, which also leaves room for improvement in future studies. Lastly, it was probably due to the research context that information insufficiency did not emerge as a significant motivator for information seeking in this chapter, as compared to other similar studies (Griffin et al., 2008; Kahlor, 2007; Kahlor et al., 2006). However, future research should consider improving measurement strategies for this construct. It might have been too demanding to ask the respondents to estimate their current knowledge level and information need related to an unfamiliar topic in a telephone survey. This difficult mental task might have forced the respondents into the most extreme answers to these two questions. In fact, over 20% of the respondents marked zero for the current knowledge item, and almost 40% marked 100 for the information need item.

With cross-sectional survey data, it is difficult to measure actual information seeking behaviors, so attention was used as a proxy measure for past information seeking activities. The decision to categorize the use of traditional media channels as routine information seeking, and the use of health websites and internet support groups as non-routine information seeking was also somewhat arbitrary. These compromises allowed for the test of theoretical propositions related to different types of information seeking, but future research should consider measuring routine and non-routine information seeking with greater precision such as via controlled experiments, in-

depth interviews, or even observations, some of which other scholars have already used (Niederdeppe et al., 2007).

Study Implications

Between the two samples, a clear distinction exists in the direction and degree of impact that risk judgment and negative emotions have on non-routine information seeking, which captures those more active information seeking behaviors such as searching through health-related websites or participating in internet support groups. Based on results from the interaction test, respondents from the two samples might have adopted different coping mechanisms when thinking about potential risks involved in clinical trials. That is, risk judgment seemed to drive the LLS respondents to engage in a “danger control” mode to obtain more information about this topic, but respondents in the national sample were more likely to turn away from additional information. These findings underscore the need to develop a clear understanding about the potential audience when designing public information campaigns. Specifically, when the target audiences are patients and their caregivers with certain level of familiarity with a health issue, focusing on risk management or using emotional appeals might attract their attention and increase information seeking. When the target audience is the general public with lower knowledge or even little awareness, however, campaign designers should probably shy away from explicit messages related to risks and refrain from strategies such as fear appeals in their initial contact with the audience. These types of messages might induce responses such as risk avoidance or fear control and consequently reduce information seeking (Leventhal, 1970; Witte, 1994), as discussed above. In contrast, since optimistic feelings were positively related to both types of information seeking across the two samples, based on the broaden-and-build theory of positive emotions (Fredrickson, 2005), embedding optimism in health messages might prompt individuals to engage

with their environments and partake in the seeking of additional information. To enhance clinical trial enrollment, for instance, campaign messages that encourage altruistic behaviors, highlight potential benefits, and emphasize positive contributions to the society at large might be effective.

Consistent with past studies, subjective norms continue to function as an important motive for information seeking behaviors. This chapter specifically focused on normative influences from doctors, family members, friends, and other important people in one's personal network. Finding that these interpersonal influences could lead to greater information seeking through mediated channels seems to speak to the "intermedia processes" that communication scholars have demonstrated in their research on media effects (Rogers, 2002). Whether the underlying motive is to maintain attitudes that are socially acceptable or to fulfill other people's anticipations, interpersonal communication about a health issue such as clinical trial enrollment seems to have the potential to facilitate the effects of media campaigns. On the other hand, in relation to improving communications about clinical trial enrollment, these findings also suggest that campaign messages could promote clinical trial participation as a socially acceptable, or even desirable, action for which even ordinary individuals should develop some awareness and understanding.

Chapter Conclusions

Overall, key findings from this chapter indicate that risk judgment, affective responses, and social normative influences motivate individuals' seeking of information related to clinical trial enrollment through routine and non-routine information channels in different ways. Further, the results suggest that the ARIS model could be applied to guide formative research for health campaigns to improve the communications of clinical trial enrollment. Guided by the RISP model, subsequent chapters will examine these two samples separately in greater details.

CHAPTER 4

MOTIVATION FOR HEALTH INFORMATION SEEKING AND PROCESSING ABOUT CLINICAL TRIAL ENROLLMENT AMONG PROSPECTIVE HEALTHY VOLUNTEERS⁵

While the last chapter primarily compared general information seeking behaviors among cancer patients and prospective healthy volunteers, it is important to probe further motivations behind not only information seeking, but also information processing activities. The current chapter, therefore, will focus on prospective healthy volunteers first to explore what might drive them to engage in these communication activities. As mentioned earlier, clinical trials are important research processes for the advancement of medical science, such as the ones conducted with cancer patients to explore “whether promising approaches to cancer prevention, diagnosis, and treatment are safe and effective” (National Cancer Institute, 2001). Past research has indicated that less than five percent of adults with cancer participate in clinical trials annually (Umutyany et al., 2008; Siminoff & Thomas, 2008). These low enrollment rates have spurred interest in detecting barriers for accrual in the research community (see, for example, Abraham et al., 2006; Albrecht et al., 2003; Mills et al., 2006; Sharp et al., 2006). In general, these barriers include patient-related factors such as lack of awareness or access, distrust, and fear due to the loss of control in a randomized trial; physician-related factors such as conflict of interest, lack of awareness and resources, uncertainty, and inadequate communication; and institutional factors such as lack of available trials and difficulty with logistics (see, for example, Avis et al., 2006; Baquet et al., 2006; Fallowfield et al., 1998; Grady et al., 2006; Harris et al., 1996; Jenkins & Fallowfield, 2000).⁶

⁵ A version of this chapter has been accepted for publication in *Health Communication*.

⁶ These barriers are reviewed more extensively in Chapter 1.

In addition, past research has identified general positive attitudes toward clinical trials despite low levels of participation. For instance, a national probability sample of 1,000 adults expressed an overall positive opinion toward clinical trials, saying that they would consider participation if given the opportunity (Comis et al., 2003). Studies that compare cancer trial participants and nonparticipants also identified positive attitudes towards clinical research in both groups (Madsen et al., 2002). In contrast, a survey of almost 6,000 people with cancer found that among those who were aware of the clinical trial option, most declined to participate, citing reasons such as fear of getting a placebo, being a “guinea pig”, or believing that standard treatment was better than what they would be offered in clinical trials (National Cancer Institute, 2001).

Some researchers have argued that improving physicians’ communication with their patients would bridge the gap between patient attitudes and behavior (Albrecht et al., 1999; Fallowfield et al., 1997; Grant, Cissna, & Rosenfeld, 2000). However, doctors are not compensated for talking to patients, and most primary care doctors have to squeeze more patients in a given amount of time to balance off increasing costs (Brody, 2008). Even when doctors are willing to talk to patients, they have to maintain a delicate balance between offering too little information, which might lead to confusion and distrust, or offering too much information, which might result in anxiety and despair (Leydon et al., 2008; Thorne, Hislop, Armstrong, & Oglov, 2008; Thorne, Hislop, Kuo, & Armstrong, 2006). An audience-based approach to communication, therefore, seems extremely important, which entails that we should try to communicate with patients or at least understand their communication behaviors better.

As a result, researchers have paid more attention to the role that patients play in this communication process. Studies have shown that when patients are involved in

treatment decisions, they experience greater perception of control and self-responsibility (Lerman et al., 1993) and improved health outcomes (Garrity & Lawson, 1989). In particular, Krupat and Irish (2007) offered an excellent review of literature that examines the “active” role that patients could play in managing their care, focusing on their desire for information, desire to be involved in decision making, and desire for emotional support. In general, these authors conclude that patients need to know how to participate in the medical decision making process to fulfill these desires. Echoing this proposition, Parker-Pope (2008) also suggests that doctors need to not only acknowledge their patients’ effort in search of more information and alternative opinion but also guide them in this process. Therefore, it seems important to improve communication about clinical trial enrollment so that the most relevant and useful information gets conveyed in the short amount of time that doctors have for each patient.

Since clinical trial enrollment entails crucial ethical concerns for medical research, communication about clinical trial enrollment encompasses much more than everyday doctor-patient interaction. Due to the uncertainties involved in clinical trials, doctors’ role as information sources for their patients seems indisputable. In fact, previous studies have identified that cancer clinical trial participants strongly value a trusting doctor-patient relationship (Catania et al., 2008; Madsen et al., 2007; Verheggen, Jonkers, & Kok, 1996). However, increasing the rate of clinical trial enrollment should not be the ultimate goal for medical researchers or doctors. There is consensus in the research community that the trial process should not override the rights and needs of a clinical trial participant, especially in relation to proper information disclosure about risks and benefits, protection of vulnerable population, and equal access to research opportunities (Beauchamp & Childress, 1994; Epstein, 2003, 2007; Stryker et al., 2006). When it comes to communication about clinical trial

enrollment, therefore, efforts should be focused on how to motivate ordinary individuals to actively seek information about clinical trial opportunities. This way, when there is a need to make a decision about enrollment, they will be prepared to join in the discussion with their doctors.

Focusing on motivations for clinical trial enrollment, past research has suggested that individuals' decisions to accept a clinical trial are influenced more by non-rational factors such as general beliefs about clinical trials, message cues, and affective evaluation of doctor-patient interactions, rather than knowledge and understanding of the clinical trial process (Curbow, Fogarty, McDonnell, Chill, & Scott, 2006). These findings seem alarming, especially when juxtaposed with evidence from health psychology research indicating that patients who use the cognitively effortful information-seeking and information-processing decisional strategies are more effective in coping with life-threatening illnesses (Petersen, Heesacker, & Marsh, 2001). If the goal of communication is to assist ordinary individuals in reaching informed decisions, not to simply persuade them to enter a trial blindly, it is even more important to study factors that influence individuals' health-related communication behaviors.

Presenting a context for this chapter, clinical trial participation offers a unique case study for risk and health communication. Even though clinical trial enrollment is likely a critical issue for medical researchers and cancer patients, most people do not view it as a topic that bears great personal relevancy (National Institutes of Health, National Cancer Institute, 1997; 2004). Therefore, when applying the RISP model to examine health information seeking and processing about clinical trial enrollment, it is very likely that potential risks involved in clinical trials would not be "readily seen as posing a direct personal threat" to most of the respondents (Kahlor et al., 2006, p. 165). On a conceptual front, therefore, this analysis also expands the evaluation of the

RISP model into the venue of impersonal risk involved in health decision making, which is likely to determine that certain components of the RISP model, such as informational subjective norms, might act as stronger motives for information seeking and processing.

Theoretical Framework

Key Components of the RISP Model in this Analysis

Since Chapter 2 has provided an overview of the RISP model and its key propositions, this section will only review those key variables that are relevant to the analysis in this chapter:

Information insufficiency (sufficiency threshold). Occupying the central part of the RISP model, this concept describes how the need to achieve information sufficiency could motivate individuals to process risk information more systematically and less heuristically or adopt a more active and non-routine type of information seeking. Previous analyses of the RISP model have found support for a relationship between information insufficiency and more effortful information seeking and processing (Griffin et al., 2004; Kahlor et al., 2003; Kahlor et al., 2006; Trumbo, 2002). In regards to clinical trial enrollment, the drive for information sufficiency could lead people to search health information from a variety of sources or seek an alternative opinion. The link between information insufficiency and information seeking, according to the RISP model, is moderated by individuals' evaluation of the validity and usefulness of existing information, termed as relevant channel beliefs.

Relevant channel beliefs. The RISP model extends HSM's account for accuracy motivation and defense motivation and posits that beliefs about the information channel that delivers risk messages would influence individuals' information seeking and processing behaviors. Past studies have mainly focused on the mass media to assess this component. Given the doctor-patient communication

context in the present chapter, individuals' overall trust in their doctors was used as a measure for channel beliefs. Previous analyses of the RISP model have examined institutional trust as part of the multi-dimensional concept of perceived hazard characteristics, emphasizing the influence of trust on an individual's overall risk perception. This analysis included trust in doctors as a proxy measure for relevant channel beliefs because trust in this context directly relates to an information source with whom the respondents personally interact. More importantly, past research has shown that a trusting doctor-patient relationship plays an important role in individuals' decisions to enroll in clinical trials (Battaglia, Ash, Prout, & Freund, 2006; Nurgat et al., 2005). Therefore, it is reasonable to argue that trust in doctors might have more direct influence on information seeking and processing, and therefore, deserves a more salient role in the RISP model than contributing as a sub-category concept. Griffin et al. (2008) have suggested future studies to explore the possibilities of reconceptualization or new measurement strategies for the relevant channel beliefs component. Thus, the current analysis also represents an exploratory effort in testing alternative measures for this construct.

Informational subjective norms. Reflecting on HSM's notion of impression motivation and Ajzen's (1988) concept of normative beliefs, the original proposition of the RISP model indicates that social expectations for individuals to stay informed could contribute to their sense of information insufficiency and, therefore, indirectly motivate effortful information seeking and processing. Recent studies have suggested a need to adjust this component's position in the RISP model because it seems to produce a more direct impact on active information seeking and processing (Griffin et al., 2008; Kahlor, 2007; Kahlor et al., 2006). In relation to clinical trial enrollment, those who believe that others who are important to them would want them to know more about clinical trial opportunities might pay more attention to relevant messages,

even when they do not wish to gather more information to meet their own need. This chapter compares the direct and indirect impact of this component.

Perceived hazard characteristics and affective responses. The RISP model proposes that affective responses result from risk perceptions, both of which then contribute to the sense of information insufficiency. However, informed by cognitive theories of emotions (Lazarus & Folkman, 1984), I believe that the “causality is bidirectional” (p. 274) between cognition and emotion. That is to say, perceived hazard characteristics and affective response are equally likely to influence each other. Previous studies based on the RISP model have found that cognitive reasoning (such as causal attribution and risk judgment) has an impact on affective responses (such as worry and anger) (Griffin et al., 2008; Griffin et al., 2004). Adding to these findings, research in communication and psychology has provided sufficient evidence that emotions could also affect cognitive activities in many different ways, especially when positive emotional states are considered (Isen, 1999, 1987; Slovic et al., 2005).

Past studies based on the RISP model have primarily examined negative emotions, which often concur with risky situations. This chapter, however, examines the impact of a positive emotion on communication behaviors related to clinical trial enrollment. There is evidence showing that positive affective state not only could foster more careful information processing (see Aspinwall, 1998 for a review), but it may also enhance individuals’ interest in potentially negative information (Trobe & Neter, 1994). Compared to negative emotions that are likely to highlight the importance to know about a potential risk, a positive affective state or association might create a greater interest or curiosity for more information. In other words, a positive affect such as feeling optimistic about clinical trial participation could bring forward a tendency or predisposition to engage in more information seeking and processing. This latter premise is also consistent with past studies that have identified

positive relationships between dispositional optimism and attention to health risk information (Aspinwall & Brunhart, 1996).

Based on social learning theory (Bandura, 1977; Rotter, 1954), Ortony and Clore (1981) have stated that a positive expectation with an unclear outcome could result in hopeful feelings. Previous research has identified the important role of a sense of optimism in facilitating treatment and maintaining positive attitude among patients (Cohen, de Moor, & Amato, 2001; Kodish & Post, 1995; Nowotny, 1991; Sardell & Trierweiler, 1993). Even unrealistic optimism has been found to act as a resource that protects individuals' mental and physical health in the context of detrimental illness (Taylor, Kemeny, Reed, Bower, & Gruenewald, 2000; Taylor, Lichtman, & Wood, 1984). Therefore, given the uncertainties embedded in clinical trial enrollment, I believe that it is important to evaluate the relative impact of risk judgment and optimistic feelings on information insufficiency and, subsequently, information seeking and processing.

Research Questions and Hypotheses

While focusing on testing the role of optimistic feelings in motivating information seeking and processing related to clinical trial enrollment, this chapter also examine relationships among other key components of the RISP model to evaluate its applicability to this context of health decision making. Based on past studies (Griffin et al., 2008; Griffin et al., 2004; Griffin et al., 1999; Kahlor et al., 2003), the following hypotheses are proposed in regards to the endogenous variables:

H1: Information insufficiency will be positively related to information seeking (H1a) and systematic processing (H1b), and negatively related to heuristic processing (H1c).

Among the exogenous variables, there has been evidence in support of direct relationships that informational subjective norms have with information insufficiency,

information seeking and systematic processing (Griffin et al., 2008; Griffin et al., 2004; Kahlor, 2007; Kahlor et al., 2006), but the relationship between informational subjective norms and heuristic processing has been less consistent. Given the context of this chapter, I believe that respondents who value other people's opinion about how much they should know about clinical trial enrollment would also be more likely to engage in systematic processing. Therefore, the second set of hypotheses is:

H2: Informational subjective norms will be positively related to information insufficiency (H2a), information seeking (H2b), systematic processing (H2c), and negatively related to heuristic processing (H2d).

Past studies have also supported a positive relationship between perceived hazard characteristics and information insufficiency in a variety of risk contexts (Griffin et al., 2008; Griffin et al., 2004). Therefore, the next hypothesis is:

H3: Perceived hazard characteristics (risk judgment) will be positively related to information insufficiency.

This chapter represents a first attempt to examine positive emotions as part of the RISP model. Even though there has been research suggesting the positive influences that optimistic feelings have on health behaviors and health decision making, how optimistic feelings will work together with risk judgment to influence the key variables remain an empirical question. In addition, given the evidence on optimistic bias (Weinstein, 1989), it is also important to study how optimistic feelings relate to risk judgment itself. Therefore, the first research question is:

RQ1: What relationship do optimistic feelings about clinical trial enrollment have with risk judgment, informational subjective norms, information insufficiency, and information seeking and processing?

Research based on the RISP model has emphasized different aspects of relevant channel beliefs, such as the information channel's trustworthiness and

usefulness (Kahlor et al., 2003). Most of the existing research, however, has focused on the mass media. This chapter examines a new context of communication to determine the role of trust in doctors, as a proxy measure for relevant channel beliefs, in motivating information seeking and processing. Therefore, the second research question is:

RQ2: How does individuals' trust in their doctors relate to their information seeking and processing about clinical trial enrollment?

Method

Sample

In the national sample, respondents ranged in age from 18 to 90 (*Median* = 50, *M* = 50, *SD* = 16). Education levels ranged from eighth grade or less to post-graduate training (mean and median level both equated to "some college"). Household income ranged from less than \$10,000 to \$150,000 or more (*Median* = \$60,000, *M* = \$54,000, *SD* = \$24,100). Among the respondents, 51% were female, and 81% were White. Compared to the 2006 American Community Survey (U.S. Census Bureau, 2007), the sample seemed to have slightly over represented individuals with higher income, but the other parameters were quite similar.

Measurement

The survey introduced clinical trials as studies that use volunteer patients to test new drugs, treatments, or new uses for approved drugs and treatments. Measures for key variables were adopted from past analyses based on the RISP model (Griffin et al., 2008; Griffin et al., 2002). The survey is reproduced in Appendix 2A; below, footnotes indicate which questions on the survey were used for each measure.

Information seeking. Intentions for information seeking and avoidance were measured with two items previously tested based on the RISP model. The avoidance

item was reverse-coded.⁷

Information processing. Six information processing items were subjected to a factor analysis (principle axis factoring, oblique rotation).⁸ Similar results emerged in comparison to past analyses (Griffin et al., 2008; Kahlor et al., 2003) of these items for heuristic processing ($\omega = .56$) and systematic processing ($\omega = .57$).⁹

To further test the validity of these endogenous variables, zero-order correlations were computed between these variables and measures of individuals' self-reported attention paid to various channels that contain information about clinical trials. All the correlation coefficients were significant in the expected directions (Table 4.1). Overall, respondents who reported greater intention for information seeking and systematic processing also indicated that they had paid more attention to information about clinical trial enrollment from a variety of information sources.

Information insufficiency. Two variables that asked respondents to assess how much they knew about clinical trial enrollment and how much they needed to know to fully understand this issue (sufficiency threshold) measured this concept. Consistent with past analyses based on the RISP model (Griffin et al., 2004), rather than using the calculated difference in absolute values between these two items to create an "information insufficiency" measure, current knowledge was entered as an exogenous variable and information sufficiency threshold as an adjacent endogenous variable. As Kahlor (2007) mentioned, this technique helped to avoid potential reliability issues

⁷ Items 15 & 17 in the questionnaire

⁸ Items 16 & 18-22 in the questionnaire

⁹ According to Carmines and Zeller (1979), omega provides the closest estimate to the true reliability of the measure (p. 62). We recognize that the reliability coefficients for the information processing items did not meet the minimal standard (.60) that other scholars have argued for (Robinson, Shaver, & Wrightsman, 1991). However, the structural equation modeling technique used in our data analysis accounts for potential measurement errors when indicating overall fit of the specified model. These measures are also consistent with past studies based on the RISP model.

and the influence of ceiling effects in current knowledge.

Table 4.1
Correlation of information seeking and processing measures (composite scales)
with attention to information (partial correlation coefficients)

Information channels	Information seeking	Systematic processing	Heuristic processing
Family	.17**	.10*	-.20*
Medical experts	.22**	.22**	-.20**
Patient advocacy groups	.17**	.19**	-.18**
Newspapers	.12*	.10*	-.13**
Health newsletters	.16**	.19**	-.14**
Websites	.21**	.14**	-.16**
Internet support groups	.12*	.13**	-.10*

* Attention to information was measured on a scale from zero (none) to ten (a lot).

Significance key: * $p \leq .05$; ** $p \leq .01$.

Relevant channel beliefs. Since most communications about clinical trial opportunities occur in interpersonal contexts between doctors and patients, this concept requires a measurement strategy that is different from most existing analyses based on the RISP model. Therefore, respondents' overall trust in their doctors was chosen as a proxy measure. To measure trust, three items ($\alpha = .70$) from past research that has demonstrated their validity and reliability were adopted (McComas et al., forthcoming).¹⁰

Informational subjective norms. This component was measured by assessing whether respondents perceive others' expectations that they should stay on top of information about clinical trial enrollment.¹¹

Perceived hazard characteristics: Risk judgment. This multi-dimensional component deals with many different aspects of risk that has included self-efficacy, causal attributions, and risk judgment among others. Since the evaluation of risk involved in clinical trials bears a lot of complexity, this analysis resorted to the most

¹⁰ Items 25-27 in the questionnaire

¹¹ Item 11 in the questionnaire

generic and arguably most frequently used measure for risk - using an estimate of the likelihood and severity of potential harm that clinical trial enrollment might induce (Gregory & Mendelsohn, 1993; Slovic, 1992).

Affective responses: Optimistic feelings. Among three other emotions, respondents indicated how optimistic they feel when they think about enrolling in a clinical trial on a scale from zero to ten.

Analysis

Data were analyzed with LISREL 8.80 structural equation modeling (SEM) program. LISREL provides tests of the adequacy of the entire model, simultaneous estimation of all structural coefficients, and tests of statistical significance for all coefficients. To test the overall model, a two-step procedure recommended by Kline (2005) was followed. Through confirmatory factor analysis, a measurement model was first specified and refined, based on which estimation of the structural model was completed. The overall goal was to find a parsimonious structural model that explained the data reasonably well (Kline, p. 217). This technique also permits greater precision in the assessment of the reliability and validity of these latent constructs (Schemer, Matthes, & Wirth, 2008).

The χ^2 goodness-of-fit statistic is reported as an index of model adequacy, where a nonsignificant value indicates good fit. Because χ^2 has been shown to be sensitive to sample size (Bollen, 1989), the χ^2/df ratio is also reported, where a value less than five indicates a good fit (Klein, p. 137). Other indices reported here include: root mean square error of approximation (RMSEA), the Comparative Fit Index (CFI), the Goodness-of-Fit Index (GFI), and the Adjusted Goodness-of-Fit Index (AGFI), which demonstrate how well the specified model accounts for the data. RMSEA values less than .05 typically indicate good fit. For CFI, GFI and AGFI (values ranging from .00 to 1.00), .90 and above is generally considered to represent good fit.

Regression coefficients for the hypothesized structural relations are reported along with their statistical significance. A probability level of $p < .05$ was used as the base level of statistical significance.

Results

The effective sample size for data analysis with list-wise deletion was 392. Through the imputation function in PRELIS, 37 more cases were added, which resulted in a final effective sample size of 429. Imputation in PRELIS substitutes the missing value of a case with a real value obtained from another case that has a similar response pattern over a set of matching variables (Jöreskog & Sörbom, 1996a, p. 153). Table 4.2 presents descriptive statistics including correlation coefficients in the upper triangle of the matrix, covariance coefficients in the lower triangle, and variances along the diagonal. The zero-order correlation matrix was generated in SPSS16.0 prior to data imputation using the raw data; the covariance matrix was generated in the PRELIS package of LISREL 8.80 after data imputation. The covariance matrix was used for SEM tests (Jöreskog & Sörbom, 1996b). To reduce potential measurement error, for those variables that were measured with a single item, an arbitrary reliability value of .85 was specified, which was equivalent to an error variance of .15 times the variance of the observed variable (Jöreskog & Sörbom, 1996b, p. 37).

Table 4.2
Descriptive statistics

Key Variables	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
1. Current knowledge	838.23	-.08	.08	.02	.19**	.12*	.21**	.16**	.11*	.11*	.16*	-.11*	-.15**	-.07	-.10*	-.00	-.03
2. Information sufficiency	-47.94	530.57	.07	.06	.04	-.05	.07	.03	.08	.01	.08	-.06	-.07	-.01	.07	.09	-.00
3. Risk likelihood	72.80	43.78	685.25	.57**	-.17**	-.10*	-.12**	-.07	-.12*	-.18**	.03	-.02	.09	-.05	-.13**	-.05	-.11*
4. Risk severity	7.33	63.28	383.56	776.52	-.21**	.01	-.10*	-.01	-.03	-.11*	-.04	-.00	.03	-.08	-.03	-.01	-.05
5. Optimistic feelings	42.16	3.84	-24.38	-29.83	7.19	.23**	.33**	.33**	.28**	.22**	.19**	-.12*	-.32**	-.16**	.09*	.05	.05
6. Subjective norms	3.56	-1.58	-2.06	-.21	1.69	1.17	.25**	.29**	.27**	.17**	.10*	-.01	-.19**	-.09*	.01	.01	.04
7. Avoidance (reverse)	6.39	.54	-1.90	-1.84	1.59	.22	1.19	.36**	.39**	.20**	.17**	-.26**	-.35**	-.29**	-.03	.02	.02
8. Seeking	4.09	.02	-.76	.41	1.65	.24	.24	1.41	.43**	.27**	.24**	-.23**	-.42**	-.24**	.02	.07	.05
9. SYS1	3.32	1.59	-1.87	-.48	1.75	.28	.36	.34	1.22	.39**	.24**	-.07	-.42**	-.21**	.03	.16**	.07
10. SYS2	5.35	1.24	-3.20	-2.71	1.99	.23	.28	.27	.57	1.25	.08	-.06	-.25**	-.15**	.09	.07	.06
11. SYS3	4.48	1.98	1.34	.70	1.04	.09	.12	.14	.20	.13	1.07	-.03	-.27**	-.08	.07	.01	-.03
12. HEU1	-3.71	-1.15	.04	-.49	-.78	.00	-.24	-.16	-.12	-.15	.00	.89	.19**	.22**	-.01	-.08	-.03
13. HEU2	-4.95	-.81	1.46	-.11	-1.89	-.18	-.30	-.26	-.36	-.29	-.17	.18	.79	.28**	-.04	.02	-.02
14. HEU3	-1.69	-.31	-.77	-1.43	-.52	-.08	-.20	-.13	-.14	-.13	-.04	.17	.15	.95	.01	.01	-.00
15. TRUST1	-2.60	1.55	-2.86	.02	.54	.02	-.01	.02	.07	.18	.06	-.03	-.03	-.01	1.26	.43**	.41**
16. TRUST2	.95	1.57	-1.21	.42	.35	.02	.04	.06	.20	.16	.04	-.08	.01	-.00	.40	.82	.49**
17. TRUST3	-.78	-.47	-2.80	-1.09	.20	.04	.01	.04	.07	.13	-.04	-.06	.01	.01	.32	.38	1.01
<i>M</i>	26.27	83.80	50.55	51.45	4.95	3.15	3.44	3.09	2.88	3.10	2.73	3.82	4.05	3.32	3.57	3.85	3.62
<i>SD</i>	28.95	23.03	26.18	27.86	2.68	1.08	1.09	1.19	1.10	1.12	1.03	.94	.89	.97	1.12	.91	1.01

* Pearson correlation coefficients are provided in the upper triangle of the matrix, variances are located on the diagonal, and covariances are reported in the lower triangle.

Significance key: * $p \leq .05$; ** $p \leq .01$.

The CFA model indicated moderate fit to the data even though the p-value was significant (Table 4.3). Based on the refined CFA model ($\chi^2 = 161.76$, $df = 79$, $\chi^2/df = 2.05$, $p < .05$, RMSEA = .049, CFI = .96), a conceptual model was specified. Results for the overall fit of the conceptual models are presented in Table 4.3. Analysis of the

overall model fit along with tests of individual paths indicated that the baseline conceptual model could be improved. After deleting non-significant paths and setting the error covariances of information seeking, heuristic processing, and systematic processing free, the final model was specified ($\chi^2 = 181.56$, $df = 95$, $\chi^2/df = 1.91$, $p < .05$, RMSEA = .046, CFI = .96). The χ^2/df ratio of 1.91 indicated a relatively good model fit to the data given the sample size.

Table 4.3
Summary of fit indicators

Models	χ^2	df	p	χ^2/df	RMSEA	GFI	AGFI	CFI
Baseline CFA model	176.33	80	<.05	2.20	.053	.95	.91	.95
Revised CFA model ^a	161.76	79	<.05	2.05	.049	.96	.92	.96
Baseline conceptual model	463.87	97	<.05	4.78	.094	.89	.82	.84
Revised model ^b	181.56	95	<.05	1.91	.046	.95	.92	.96

*RMSEA = root mean squared error of approximation; GFI = Goodness-of-Fit Index; AGFI = Adjusted Goodness-of-Fit Index; CFI = Comparative Fit Index.

a. Revision from baseline CFA model to final CFA model: added error covariance between two heuristic processing measures.

b. Revision from baseline model to final model: deleted nonsignificant paths and set the error covariances between systematic processing, heuristic processing, and information seeking free.

Error variances of the three endogenous variables were allowed to covary because those who actively search for more information about clinical trial enrollment are also likely to pay more attention to existing information and process it more carefully. Past analyses of the RISP model have examined these three variables as dependent variables in separate multiple regression models, but theoretically, they should relate to each other. On the other hand, both the factor analysis and the measurement model fit index indicated that discriminative validity among these variables was assured. After adding these error covariances, the overall fit of the model improved substantially. As reported in Table 4.3, GFI, AGFI, and CFI all

exceeded the conventional value of .90, indicating good fit. RMSEA also reached the conventional cutoff value of .05. HLM analysis based on the raw data was also conducted to examine the robustness of the results obtained from SEM modeling, and the results held consistent for the most part. The unstandardized regression coefficients obtained from HLM path analyses are displayed in parentheses next to the standardized structural coefficients generated in SEM analyses in Figure 4.1.

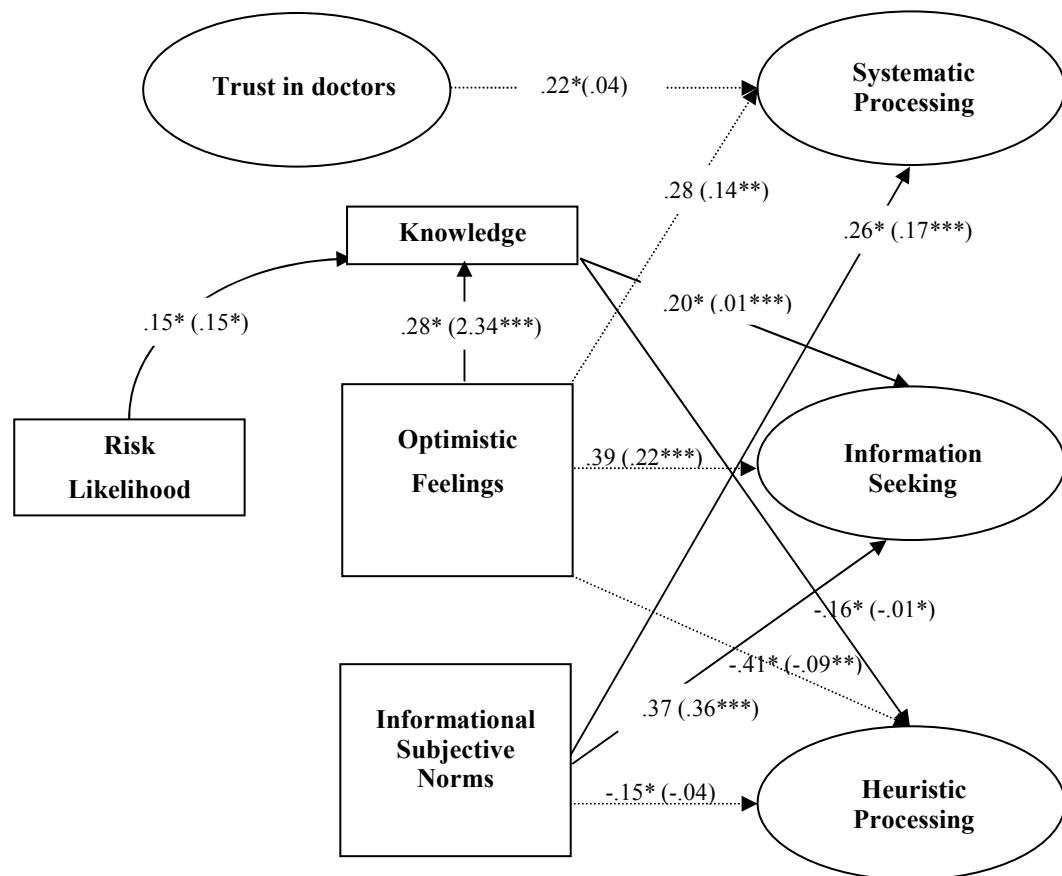


Figure 4.1

Results for the conceptual model with statistically significant paths

* The standardized solution from structural equation modeling (SEM) analysis and the unstandardized solution from hierarchical linear modeling (HLM) path analysis are reported, with the latter in parentheses.

To enhance the readability of the figure, only paths with significant regression coefficients and t-values are displayed. Different from the hypothesized positive relationships, after current knowledge was controlled, information sufficiency threshold did not relate to any of the endogenous variables to a statistically significant degree. Rather, current knowledge was positively related to information seeking ($\beta = .20, t = 3.44, p < .05$) and negatively related to heuristic processing ($\beta = -.16, t = 2.85, p < .05$). Therefore, H1a through H1c were not supported. On the other hand, informational subjective norms significantly related to information seeking ($\beta = .37, t = 5.42, p < .05$), systematic processing ($\beta = .26, t = 4.23, p < .05$), and heuristic processing ($\beta = -.15, t = 2.15, p < .05$). Therefore, H2b through H2d were supported. Neither current knowledge nor information sufficiency threshold was significantly related to informational subjective norms, even though the zero-order correlation indicated a marginal relationship between current knowledge and informational subjective norms ($r = .12, p < .05$). For the two variables that measured perceived hazard characteristics, only risk likelihood was significantly related to current knowledge ($\beta = .15, t = 2.71, p < .05$), so H3 was partially supported.

To answer the research questions, optimistic feelings were significantly related to current knowledge ($\beta = .28, t = 5.29, p < .05$), information seeking ($\beta = .39, t = 6.00, p < .05$), systematic processing ($\beta = .28, t = 4.71, p < .05$), and heuristic processing ($\beta = -.41, t = 6.07, p < .05$). The paths between optimistic feelings and perceived hazard characteristics were not significant, even though correlation coefficients based on the raw data suggested negative relationships between optimistic feelings and risk likelihood ($r = -.17, p < .001$) and risk severity ($r = -.21, p < .001$).

Trust in doctors, as a proxy measure for relevant channel beliefs, did not exhibit a significant relationship with information seeking or heuristic processing, but

it did show a positive relationship with systematic processing ($\beta = .22, t = 4.14, p < .05$). Overall, the structural model explained 46% of the variance in information seeking, 25% of the variance in systematic processing, and 29% of the variance in heuristic processing. These results are comparable to past analyses of the RISP model in different contexts (Griffin et al., 2008; Kahlor et al., 2006).

Discussion

This chapter applies the RISP model to examine communication behaviors such as information seeking and processing related to clinical trial enrollment. By recognizing the uncertainties embedded in clinical trial results, clinical trial enrollment was viewed as a case study of risk. This analysis examined the relative influences on information seeking and processing from individuals' self-assessed current knowledge about this topic, need for more information, risk judgment, normative beliefs, affective responses, and overall trust in their doctors. Overall, the model achieved adequate fit to the data, even though some of the hypothesized relationships were not supported. Compared to a cognitive need for more information, optimistic feelings and normative beliefs seem to exert greater impact on individuals' information seeking and processing. These findings seem to reflect past research showing that non-rational factors, such as general attitudes toward clinical trials, tend to have stronger influence than knowledge on people's decisions about clinical trial participation (Curbow et al., 2006). However, there are also broader implications of these results both theoretically in regards to the RISP model, as well as practically in relation to communication about clinical trial enrollment.

First, even though clinical trial enrollment is an important issue for the medical research community and cancer patients who might view trials as their final option, the public's overall awareness and interest in this topic are much more tepid. In fact, over half of the respondents in the national sample said they had never heard about

clinical trial opportunities or had only heard a little about this issue. Therefore, clinical trial enrollment was not a topic that bore much relevancy or salience among these respondents, which might explain why some of the relationships that past analyses of the RISP model have identified did not emerge in this chapter. For instance, for cancer patients, clinical trial participation might carry many forms of risks such as the probability of receiving a placebo rather than the treatment, the potential of enduring side-effects, or the chance to jeopardize a good relationship with their primary care doctors. None of these risks might seem tangible for survey respondents who were mostly healthy adults (only a third of the respondents reported having ever been diagnosed with a chronic or acute illness). In this sample, risk severity judgment was the only variable that had more than 10% missing responses, which also seemed to support this conjecture. Thus, only risk likelihood judgment was significantly related to individuals' current knowledge about clinical trial enrollment. After current knowledge was controlled, neither dimension of risk perception had a significant impact on these respondents' sense of information sufficiency. Nonetheless, those who reported knowing more about clinical trial enrollment also seemed to believe that enrolling in a clinical trial could put their health at risk, which was an interesting finding on its own.

Optimistic feelings exhibited the strongest relationships with all three endogenous variables. These results indicated that those who felt more optimistic when thinking about clinical trials were also more likely to actively gather information about this topic and process it more systematically and less heuristically. Theoretically, these findings supported the inclusion of this positive emotion as part of the affective responses component in the RISP model, when examined within an appropriate research context. Optimistic feelings also had both a direct impact on information seeking and an indirect impact through current knowledge, even though

the direct relationship was much stronger. These findings suggest that an emotional response to a risky issue not only contributes to one's greater motivation for information seeking, but also cues into the assessment of one's current level of knowledge and information about this topic.

More importantly, consistent with Lazarus and Folkman's (1984) notion of emotion-focused form of coping, optimistic feelings about clinical trial enrollment also guided these respondents' decisions about the information processing strategies they need to employ to deal with this issue. In this case, optimistic feelings about clinical trial enrollment seem to serve as an important "psychological resource" for coping with the intrinsic uncertainties embedded in clinical trials because of the potential to get effective treatment or contribute to medical research. Interestingly, even though optimistic feelings were negatively related to the judgment of potential risk involved in clinical trials, they did not direct individuals' attention away from clinical trial information or make the act of processing this information seem trivial. Similar to other strong negative emotions such as worry and anger, more optimistic feelings actually led to more effortful information seeking and processing among these respondents. These results suggest that when communicating about an issue that does not pose immediate or personal threat to the well-being of the audience, emotional or attitudinal factors might serve as stronger motives for communication behaviors.

Consistent with past studies, rather than having an indirect relationship with information seeking and processing through information insufficiency, informational subjective norms had more direct relationships with these variables. Specifically, those who believe that people who are important to them would want them to stay on top of information about clinical trial opportunities also tend to engage in more effortful information seeking and processing about this topic. Similar to other tests of the RISP model in settings such as fish consumption and drinking water quality as related to

health risks (Griffin et al., 2004; Kahlor et al., 2003), or the adoption of renewable energy (Griffin et al., 2005) and information seeking about global warming (Kahlor, 2007) as related to the environment, normative beliefs continue to shape individuals' decisions about whether and how they should attend to risk information. More importantly, social norms seem to play an even greater role in the communication of clinical trial enrollment because these respondents' personal needs for more information were rather limited.

Tested as a new measure for relevant channel beliefs in this context of health decision making, trust in doctors was studied together with the endogenous variables. Results indicated that those who had greater trust in their doctors were also more likely to process information about clinical trial enrollment carefully, but this trusting relationship did not translate into more active acquisition of new information on this topic. These findings indicated a potential to use trust measures to assess individuals' beliefs about information channels and the quality of messages that they deliver. However, even though these respondents said that they paid the most amount of attention to health information coming from medical experts ($M = 7.64$, $SD = 2.54$, on a ten-point scale), doctors might not be the only source for information about clinical trial opportunities. Among the information channels included in this questionnaire, family members and patient advocacy groups also received attention from these respondents. Therefore, to refine the measurement for this component of the RISP model, it seems important to take into account the type of information channel involved in the context of the analysis. When mass media channels are the primary sources of information, as in past research contexts in which the RISP model were tested, an assessment for the validity and usefulness of the message might be sufficient. However, when mass media and interpersonal communication channels seem equally important, it is necessary to measure the relational aspect of beliefs

related to specific information channels, such as trust in the source of information.

Limitations

With the focus on motivations, contributions from one's perceived capacity to gather information about this topic might have been left out. For instance, past studies have shown this construct to strongly influence people's decisions to gather more information and determine their ability to process this information (Griffin et al., 2002). Given the length of the questionnaire, both optimistic feelings and informational subjective norms were measured with a single item. Even though appropriate procedures were followed to minimize possible measurement error in the SEM analysis, these simplistic measures might have compromised the explaining power of the analyses. The overall model might account for additional variances in information seeking and processing if these remedies were taken. Future studies should also consider extending the relevant channel beliefs measure to include alternative channels such as the internet as important information sources for clinical trial enrollment.

Consistent with past research, current knowledge was controlled for while the impact of information sufficiency threshold was evaluated. However, since almost half of the respondents marked the highest value in their responses to information sufficiency threshold, this technique did not seem effective in avoiding the impact of ceiling effects. Subsequent analysis attempted to normalize the distribution of information sufficiency threshold or use asymptotic covariance matrix for the SEM analysis, but results from either route were similar to the ones reported. Asking these respondents to assess their current knowledge and information need about clinical trial enrollment could be rather demanding tasks during a telephone survey. For those respondents who were predominantly healthy adults, this lack of variation in the perceived need for information sufficiency about clinical trial enrollment seemed to

have limited the explaining power of this construct. Lastly, since there is a lack of consensus about how to include control variables in a conceptual model for SEM analysis, the block of “individual characteristics” variables was not included, which have been found to explain a decent amount of variance in the formulation of the RISP model.

In general, this chapter’s most important findings lie in the evidence that affective responses and normative beliefs influence likely communication behaviors not only through moderating individuals’ cognitive need for information sufficiency but also on their own. These variables have consistently showed an impact on information seeking and processing even when little within-audience variation exists in terms of information need. As mentioned earlier, the goal in this research project is not to target those individuals who are most likely to become clinical trial participants and persuade them to volunteer. Rather, it is important to identify factors that draw people’s attention to this issue and use these findings to prepare them for active involvement in health decision making. These results provide valuable insight on how to improve communication about clinical trial enrollment.

Practical Implications

In our society, increasing privatization of medical research is producing more and more proprietary knowledge, and the spread of health information is getting overwhelming (Clarke, Shim, Mamo, Fosket, & Fishman, 2003). As health and risk communicators, we need to guide ordinary individuals through this storm of information and help them form the best decision possible about treatment option and health care. To do this, it is important to take an audience-based perspective to examine what truly matters in people’s decisions to gather more information on a particular topic. As mentioned earlier, clinical trial enrollment is not an issue that attracts great attention from the public unless a major breakthrough in scientific

research occurs or a dramatic event takes place. Most of the respondents reported very low levels of knowledge about this topic, and over half of the respondents said that they need to know “everything there is to know” to fully understand this issue. Therefore, to communicate about clinical trial enrollment, it is not enough just to provide more information. As shown in the data, even though most people are aware that a discrepancy exists between how much they already know and how much they need to know about clinical trials, people will be unlikely to take action to fill this gap unless this issue becomes relevant and important to them.

To break through this initial barrier for communication, we need to explore other means to introduce clinical trial opportunities to the general public. Based on results from this chapter, a general sense of optimism and the desire to fulfill social expectations seem to drive communication behaviors related to clinical trial enrollment. Therefore, messages that emphasize certain components of hope might prove beneficial. As Nowotny (1991) proposed, these components could include confidence in the outcome, helping others and getting help from others, belief in the possibility of a future good, and active involvement in setting a goal. These aspects of hope also reflect Lazarus and Folkman’s theory on the reappraisal of positive emotions such as a generalized belief that an individual has the potential and capacity to control the process, get efficacious treatment, and achieve a positive outcome. Based on these ideas, information about clinical trial enrollment could highlight the researchers’ competence in conducting the study and success rates based on past research, the importance of helping others through participation, and an individual’s ability to perform the action. Creating an environment in which more information about this topic is viewed as desirable might also stimulate greater interest in this issue.

Chapter Conclusion

To improve the communications of clinical trial research, it is important to increase awareness among the general public because healthy volunteers form an important pool of prospective subjects. More importantly, those who are generally healthy might not have the same level of understanding about the clinical trial procedure as compared to patients of cancer and other terminal diseases. Based on results from this chapter, the RISP model seems to have some applicability in explaining what cognitive and affective factors work together to motivate greater information seeking and processing about clinical trial enrollment among this sample of potential healthy volunteers. Echoing past research on this topic, non-rational factors such as emotional responses and anticipation from others seem to drive these respondents' communication behaviors more than a personal need for information sufficiency. Based on these results, communication about clinical trial enrollment should focus on the maintenance of hope and the formation of social norms so that more people might pay attention to information about clinical trial enrollment. Acquiring more information about this topic will eventually help most individuals make better decisions about clinical trial participation. Moving on to the cancer patients in the LLS sample, the next chapter will primarily focus on their decisions to enroll in a future trial since general awareness and past experience are both relatively high among these respondents.

CHAPTER 5

FROM INFORMATION PROCESSING TO BEHAVIORAL INTENTIONS:

EXPLORING CANCER PATIENTS' MOTIVATIONS FOR CLINICAL TRIAL ENROLLMENT¹²

Given their general positive attitudes, high awareness and past experience with clinical trial research, when focusing on cancer patients, motivations for communication behaviors such as information seeking and processing seem a less pressing issue, as compared to factors that actually shape their decisions to participate in a future trial. This chapter, therefore, will explore what happens after the acquisition of information among cancer patients. According to the American Cancer Society (2008), cancer accounts for nearly 25% of deaths in the United States, taking the lives of more than 1,500 people per day. Even though clinical trials represent the most important step in the process of discovering better therapies and improving cancer prevention and diagnosis, less than five percent of adults nationwide enroll in clinical trials when up to 20% are eligible (National Cancer Institute, 2006). Past research has identified an overall lack of awareness about available trial opportunities among cancer patients and healthy adults alike (Barrett, 2002; Crosson, Eisner, Brown, & Maat, 2001; Roberson, 1994). Improving clinical trial awareness, not surprisingly, has been one strategy used to increase accrual rates (Lara et al., 2005). Simply focusing on awareness, however, may not address other barriers to enrollment. For example, some research has found that among newly diagnosed cancer patients who were eligible for trials, 49% declined to participate when approached by their physicians, citing reasons such as geographical distance, fear of randomization, and concerns with payment or

¹² A version of this chapter has been accepted for presentation to the Health Communication Division of the National Communication Association Annual Convention in Chicago, IL, November 2009.

insurance coverage (Lara et al., 2001).

These and other studies suggest that understanding patients' attitudes is an important first step in the communication process. For example, a recent national survey found that respondents' knowledge and understanding of the clinical trial procedures were related to positive attitudes towards clinical trial participation (Comis et al., 2003). Several other studies have found similar results (Baquet et al., 2006; Ellis, Butow, Tattersall, Dunn, & Houssami, 2001).

Focusing on cancer patients, past research has identified many individual or social factors that could motivate or deter them from participating in a clinical trial. These findings can be categorized into cognitive evaluations of potential risks and benefits related to participation (Abraham et al., 2006; Avis et al., 2006; Daugherty et al., 1995; Jones et al., 2006; Linden et al., 2007; Mettlin, Cummings, & Walsh, 1985; Stryker et al., 2006; Verheggen, Nieman, & Jonkers, 1998); affective responses such as anxiety, fear, worry, and discomfort related to randomization, placebo, side effects, as well as hope for therapeutic benefits (Bevan, Chee, Mcghee, & Mcinnes, 1993; Catania et al., 2008; Daugherty et al., 1995; Madsen et al., 2002; Meropol et al., 2007; Mills et al., 2006); and relational concerns such as a trusting physician-patient relationship and perceived influences from other people in one's personal social network, such as family members and friends (Agrawal et al., 2006; Catania et al., 2008; Gordon & Daugherty, 2001; Grady et al., 2006; Howerton et al., 2007; Jenkins & Fallowfield, 2000; Linden et al., 2007; Madsen et al., 2007; Nurgat et al., 2005; Verheggen et al., 1996; Yeomanskinney et al., 1995).

Compared to healthy volunteers, cancer patients may have greater occasion to encounter information about clinical trials, either from their physicians, specialists, or other support services. They may also seek out information in the media and over the Internet. It is crucial to study how cancer patients deal with information about clinical

trial enrollment and how these information processing styles influence their attitudes toward clinical trials and subsequent behavioral intentions to participate. To generate results with meaningful practical implications, we also need to consider what individual and social factors work together to shape these attitudes and behavioral intentions. This chapter, therefore, tests a theoretical proposition that links relevant constructs of the RISP model and the TPB in an attempt to better account for cancer patients' motivations for clinical trial participation.

Theoretical Framework

Key Components of the RISP Model in this Analysis

As mentioned earlier, the RISP model seems like a pertinent theoretical framework to examine communication issues related to clinical trials because it integrates various cognitive, affective, and relational factors that past research has identified to urge or discourage potential participants to pay attention to information about clinical trials. Specifically related to clinical trial enrollment, the relevant components of the RISP model include:

Information sufficiency threshold. This concept follows the HSM's assumption of a validity-seeking motive and describes how the need to achieve information sufficiency could drive cancer patients to invest in more cognitive resources to process clinical trial information. Previous analyses of the RISP model have generally supported the proposition that a need for information sufficiency will lead to more effortful information processing (Griffin, Neuwirth et al., 2004; Griffin et al., 2002; Kahlor et al., 2006; Kahlor et al., 2003).

Relevant channel beliefs. This concept relates to the individuals' beliefs about the message's channel. Since the RISP model was originally proposed under the assumption that the mass media convey most risk information to the general public, it incorporates ideas from classical communication theories that describe how the

audiences select media channels to gratify their varying needs (Katz, Blumler, & Gurevitch, 1974). Past tests of the RISP model have mainly focused on how perceived usefulness, accessibility, and trustworthiness of the relevant channel influence information processing behavior (Kahlor et al., 2003). In the context of clinical trial communication, however, most people still rely on their doctors as primary source of information (Castel et al., 2006; Comis et al., 2003; Crosson et al., 2001). Therefore, this component of the RISP model warrants some conceptual adaptation. Specifically, based on past research, cancer patients' trust in their doctors seems to greatly influence their decisions to enroll in a clinical trial (Grady et al., 2006; Jenkins & Fallowfield, 2000). Consequently, this analysis will operationalize this construct by measuring cancer patients' general trust in their doctors as channels of health information.

Perceived information gathering capacity. Similar to other dual-process theories, the HSM assumes that besides motivation, capacity is also an important determinant of systematic processing. Based on the HSM, the RISP model also suggests that individuals' perceived information gathering capacity is likely to moderate the relationship between the validity-seeking motivation for sufficiency and information processing. Specifically related to this research context, this analysis will focus on cancer patients' perceived capacity to locate and comprehend information about clinical trial enrollment.

Informational subjective norms. Besides seeking validity to achieve information sufficiency, the desire to defend particular attitudinal positions and the desire to form or hold socially acceptable attitudinal positions could also motivate systematic processing (Chaiken et al., 1989; Eagly & Chaiken, 1993). The RISP model incorporates these alternative motives through the informational subjective norms component, which suggests that individuals' information processing may be

motivated by what they believe others, who are close to them, would expect them to know. Recent studies have presented evidence in support of this proposition (Griffin et al., 2008; Kahlor, 2007; Kahlor et al., 2006). In relation to clinical trial enrollment, cancer patients who believe that others who are important to them would want them to know more about clinical trial opportunities might pay more attention to relevant messages.

Perceived hazard characteristics. The RISP model also proposes that cognitive evaluations of a potential risk, defined through a multidimensional construct which includes risk judgment, institutional trust, personal control, and causal attribution, could contribute to one's sense of information sufficiency and indirectly influence information processing. Previous studies based on the RISP model have mainly tested these propositions step-by-step, showing significant relationships between different components of perceived hazard characteristics and affective responses such as worry and anger (Griffin, Neuwirth et al., 2004; Griffin et al., 2008). The results from these studies suggest that risk judgment seems most consistent across different research contexts in representing this construct and showing significant relationships with information processing. In the present chapter, since clinical trial enrollment involves a wide range of risk factors that would be difficult to assess on an individual basis, this broadly defined and frequently used approach will be used.

Affective responses. Social psychology research has accumulated a vast amount of evidence showing that both positive and negative affects could motivate systematic processing (Aspinwall, 1998; Bless & Schwarz, 1999; Clore, Schwarz, & Conway, 1994; Isen, 1999, 2004; Schwarz & Bohner, 1996). Recent development of the RISP model have identified indirect and direct relationships between affective responses and systematic processing (Griffin et al., 2008; Kahlor, 2007). However, very few studies have examined the influence of discrete emotions on information

processing in field settings (Griffin, Neuwirth et al., 2004), and even fewer studies have compared the relative impacts of negative and positive emotions. Further, even though the RISP model's original propositions acknowledged that positive affects could impact information processing, past studies have only examined negative emotions. This chapter is less interested in how an induced positive or negative affective state would influence information processing. Rather, it mainly assess whether negative and positive affective associations with the risk issue would make cancer patients more likely to incorporate clinical trial information into their health decision making process and influence their overall attitudes and behavioral intentions toward clinical trial enrollment.

This comparison is meaningful because even though negative emotions are likely to highlight a need for greater attention to specific risk information (Bless & Schwarz, 1999), evidence suggests that positive emotions could also enhance individuals' interest in potentially negative information (Aspinwall & Brunhart, 1996; Trope & Neter, 1994). In the current chapter, three negative emotions and one positive emotion were examined. With the exception of optimistic feelings associated with clinical trial participation, most existing literature has only identified negative emotions, such as fear, worry, and anxiety, as having an impact on cancer patients' decisions to participate in clinical trials (Catania et al., 2008; Jenkins & Fallowfield, 2000; Madsen et al., 2002; Meropol et al., 2007; Mills et al., 2006; Schain, 1994; Sharp et al., 2006). These negative and positive emotions are expected to influence belief-based attitudes and behavioral intentions in different ways. Specifically, while negative emotions are likely to decrease the amount of positive attitudes that cancer patients associate with clinical trials and potentially deter them from participation, positive emotions such as optimistic feelings might make them more interested or curious about clinical trials and therefore, more willing to deal with the intrinsic

uncertainties involved in clinical trials.

Linking the RISP model with the TPB

Since the RISP model has laid out key individual and social factors that contribute to people's decisions to process risk information more systematically and less heuristically, in an examination of cancer patients' motivations for clinical trial enrollment, linking the RISP model with the TPB also help to draw connections between patients' communication behaviors, attitude formation, and behavioral intentions more effectively. The MODE model (Fazio, 1986) has similar propositions, assuming that different information processing strategies could activate general attitudes in different manners, which in turn, could influence specific behaviors consistent with perceptions of the attitude object. Thus, the aim of this chapter is to investigate whether key components of the RISP model would exert similar influences on cancer patients' attitudes and behavioral intentions related to clinical trial enrollment. On the conceptual front end, testing the impacts of different information processing styles on attitude formation and behavioral intentions also represents one of the first attempts to empirically test how these communication behaviors "might ultimately affect individuals' risk-related behaviors" (Griffin et al, 1999. p. S230).

Specifically, the TPB suggests that attitudes toward the behavior, subjective norms, and perceived behavioral control serve as antecedents to behavioral intentions (Ajzen & Albarracin, 2007). Consistent with the original proposition of the relationship between the RISP model and the TPB (Griffin et al., 2002), to examine cancer patients' decisions to enroll in clinical trials, the current chapter will primarily focus on the impact of RISP constructs on individuals' belief-based attitudes (behavior-based beliefs by corresponding evaluations) and behavioral intentions related to clinical trial participation (Ajzen, 1991). Past studies informed by the TPB have accumulated robust evidence showing that "attitudes correlate strongly with

behavior when they are assessed at the same level of generality or specificity” (Ajzen, 2004). However, TPB critics have pointed out that this reasoned action approach assumes rationality and ignores the role of emotion in the prediction and understanding of human behavior. In response, Fishbein (2007) argued that the reasoned action approach actually allows one to determine exactly how emotions influence a given behavior, either as a measure of attitude, outcome expectancies or as a “distal variable that influences behavior directly or indirectly”. Thus, this chapter explores the role that emotion might play in influencing cancer patients’ belief-based attitudes and behavioral intentions.

Hypotheses and Research Questions

While primarily focusing on how systematic and heuristic processing influence cancer patients’ attitudes and behavior intentions related to clinical trial enrollment, this chapter also tests how other parts of the RISP model contribute to these TPB constructs, especially when both negative and positive emotions are present as part of the model. Based on past studies (Griffin et al., 2008; Griffin et al., 2004; Griffin et al., 1999; Kahlor et al., 2003), the following hypotheses were posited:

H1: Systematic processing will be positively related to cancer patients’ positive belief-based attitudes (1a) and intent to participate in clinical trials (1b).

H2: Heuristic processing will be negatively related to cancer patients’ positive belief-based attitudes (2a) and intent to participate in clinical trials (2b).

H3: Positive belief-based attitudes will be positively related to cancer patients’ intent to participate in clinical trials.

As one of the first studies to examine negative and positive emotions together, no directional hypotheses were drawn because mixed evidence still exists. Therefore, the first research question was:

RQ1: What relationships will negative and positive emotions have with cancer

patients' belief-based attitudes and intent to participate in clinical trials?

Linking the RISP model to the TPB, this analysis also examined the amount of variance that other RISP components explained in cancer patients' attitudes and behavioral intentions related to clinical trial enrollment:

RQ2: What are the relationships between other RISP components and cancer patients' belief-based attitudes and intent to participate in clinical trials?

Lastly, this chapter also looked at how demographic variables and individual characteristics such as a patient's health status influence their belief-based attitudes and behavioral intentions.

RQ3: How do demographic variables and individual characteristics relate to cancer patients' belief-based attitudes and intent to participate in clinical trials?

Method

Data

To construct a patient sample for the current analysis, only those respondents who have had cancer diagnosis were included, which was over 80% of the LLS sample ($N = 411$).

Measurement

Measures for key variables were adopted from past analyses based on the RISP model (Griffin et al., 2008; Griffin et al., 2002). The full questionnaire is reproduced in Appendix 2B; specific items used for each variable are indicated below in footnotes.

Information processing. Factor analysis (principle axis factoring, oblique rotation) of six information processing items generated two factors with two higher-loading items each.¹³ Summed scales were then created for systematic processing

¹³ Items 16, 18-22 in the questionnaire

(omega = .48, $M = 8.52$, $SD = 1.32$) and heuristic processing (omega = .44, $M = 4.84$, $SD = 1.75$) for further analysis. To test the validity of these scales, zero-order correlations were conducted between these variables and measures of individuals' self-reported attention paid to various channels that contain information about clinical trials. All the correlation coefficients were significant in the expected directions (Table 5.1). Overall, respondents who reported greater intention for systematic processing also indicated that they had paid more attention to information about clinical trial enrollment from a variety of information sources.

Table 5.1
Correlation of information processing measures (composite scales) with attention to information

<i>Information Channels</i>	Systematic processing	Heuristic processing
Family	.27**	-.16**
Friends	.18**	-.13*
Medical experts	.20**	-.04
Newspapers	.18*	-.14**
Radio / TV	.15**	-.13**
Health newsletters	.19**	-.12**
Websites	.15**	-.13**
Internet support groups	.15**	-.14**

* Attention to information was measured on a scale from zero (none) to ten (a lot).
Significance key: * $p \leq .05$; ** $p \leq .01$.

Information insufficiency. On scales from zero to 100, information insufficiency was measured with two variables that asked respondents to assess how much they knew about clinical trial enrollment and how much they needed to know to fully understand this issue (information sufficiency threshold). Consistent with past analyses based on the RISP model (Griffin et al., 2008; Griffin et al., 2004), this

chapter did not use the calculated difference in absolute values between these two items to create an “information insufficiency” measure but controlled for current knowledge in the regression model. As Kahlor (2007) advised in her analysis, this technique helps avoid potential reliability issues and the influence of ceiling effects.

Relevant channel beliefs. To adapt to the current research context, this chapter used three previously-tested items (McComas et al., forthcoming) to measure cancer patients’ general trust in their doctors as a measure for relevant channel beliefs.¹⁴ These items were checked for reliability ($\alpha = .65$) and subsequently combined for analysis ($M = 12.22$, $SD = 2.24$).

Perceived information gathering capacity. To assess this construct, this chapter measured cancer patients’ perceived ability to locate relevant information, as well as their perceived efficacy to comprehend this information ($r = .22$, $p < .001$).¹⁵ They were summed to create a capacity scale ($M = 6.77$, $SD = 2.93$).

Informational subjective norms. This chapter also examined whether cancer patients perceive that others important to them expect them to stay on top of information about clinical trial enrollment ($M = 3.90$, $SD = 1.06$).

Perceived hazard characteristics: Risk judgment. On scales from zero to 100, risk judgment was measured based on an estimate of the likelihood ($M = 48.28$, $SD = 24.95$) and severity of potential harm ($M = 52.43$, $SD = 25.85$) that clinical trial enrollment might involve. The risk judgment scale (likelihood * severity) based on raw scores was a bit skewed (skewness = 1.07, kurtosis = 1.13), so a new scale was created based on square root transformation for further analysis ($M = 48.32$, $SD = 23.34$, skewness = -.20, kurtosis = -.23).

¹⁴ Items 25-27 in the questionnaire

¹⁵ Items 23 & 24 in the questionnaire

Affective responses. Respondents indicated on 10-point scales how optimistic, afraid, worried, and anxious they feel when thinking about enrolling in a clinical trial. Reliability among the three negative emotions was sufficient ($\alpha = .93$) so that they were condensed to create a negative affect scale ($M = 16.72$, $SD = 8.35$). This scale was negatively correlated ($r = -.19$, $p < .001$) with optimistic feelings ($M = 6.93$, $SD = 2.06$).

Belief-based attitudes. Respondents indicated their agreement with five statements describing beliefs associated with clinical trial enrollment ranging from financial concerns to altruistic reasons.¹⁶ These beliefs were included because past studies have identified them as among the most salient beliefs cancer patients have cited when expressing their willingness or reluctance to enroll in clinical trials (Comis et al., 2003; Schain, 1994). Belief-based attitudes were measured by linking these beliefs with their corresponding evaluations.¹⁷ These attitudes were also condensed into a single scale ($\alpha = .76$), with higher scores indicating more positive attitudes toward clinical trial participation ($M = 79.51$, $SD = 18.03$). As the key dependent variable, this scale satisfied the normality assumption for regression analysis (skewness = .06, kurtosis = .03).¹⁸

Behavioral intention. This variable examined cancer patients' self-reported intent to participate in a future trial ($M = 4.26$, $SD = .86$, skewness = -1.07, kurtosis = .57).¹⁹

¹⁶ Items 29-33 in the questionnaire

¹⁷ Items 34-38 in the questionnaire

¹⁸ To ensure discriminant validity (Campbell & Fiske, 1959), correlations among measures of positive attitudes (average $r = .36$, ranging from .19 to .81) were compared to those between optimistic feelings and positive attitudes (average $r = .27$, ranging from .14 to .36). The lower inter-variable correlation indicates that the item used to measure optimistic feelings was indeed measuring a construct that differs from positive attitudes related to clinical trial enrollment.

¹⁹ Item 3 in the questionnaire

Demographic variables included age ($M = 53.95$, $SD = 12$, ranging from 21 to 86), gender (55.7% female), education from 1 = eighth grade or less to 7 = post-graduate training ($M = 5.54$, $SD = 1.40$), with the largest group being those with post-graduate training, and household income from less than \$10,000 to \$150,000 or more ($M = \$58,700$, $SD = \$21,610$). Other individual characteristics included: (a) awareness of clinical trial opportunities measured from 0 = never heard about opportunities to 4 = heard a great deal ($M = 2.42$, $SD = 1.21$, only 5% have never heard about clinical trial opportunities); (b) prior experience with clinical trials (42.2% have enrolled before); and (c) visits to doctors in the past 12 months ($M = 46.94$, $SD = 55.79$, ranging from zero visits to daily visits).

Analysis

Hierarchical ordinary least squares (OLS) regression was employed to test hypotheses and examine research questions. Hierarchical OLS allowed for the entry of these variables in a series of blocks with the results at each step indicating the relative influence of the variables on the dependent variable while controlling for variables entered in previous steps (Cohen et al., 2003). Variables in each block were entered together.

To test hypotheses using attitudes as the dependent variable, individual characteristics were entered in the first block, followed by RISP components in subsequent blocks, and heuristic or systematic processing as the final block. To test hypotheses using the intent to participate in clinical trials as the dependent variable, the independent variables were entered in the same sequence as above and added the final block, belief-based attitudes.

Results

The first set of hypotheses predicted that systematic processing would be positively related to cancer patients' positive belief-based attitudes (H1a) and intent to

participate in a future trial (H1b). The first regression model, which controlled for demographics and other dependent variables of the RISP model, confirmed a positive, significant relationship between systematic processing and positive attitudes toward clinical trials, but not to the intent for participation. Thus, H1a was supported but not H1b.

The second set of hypotheses predicted that heuristic processing would be negatively related to cancer patients' positive belief-based attitudes (H2a) and intent to participate in clinical trials (H2b). The results showed that heuristic processing was not significantly related to either one of the dependent variables. Therefore, neither H2a nor H2b were supported.

H3 predicted that positive attitudes would be significantly related to behavioral intentions. Consistent with the TPB, in both regression models, controlling for all the RISP variables, positive attitudes were consistently related to behavioral intentions in the positive direction (Table 5.2). Therefore, H3 was supported. Overall, these results seemed to indicate that patients who were more likely to process clinical trial information in a consistent and effortful manner were also more likely to hold positive attitudes toward participation. However, when both systematic processing and positive attitudes were present in the regression model with participation intention as the dependent variable, positive attitudes seemed to drive respondents' decisions to participate in a future trial.

Table 5.2**OLS regression analysis for belief-based attitudes and behavioral intention**

(Standardized regression coefficients (betas) except where indicated)

	Belief-based Attitudes		Behavioral Intention	
Individual characteristics				
Age	-.02	-.02	.04	.05
White	-.01	-.01	-.02	-.02
Gender	-.06	-.08	-.03	-.04
Income	.07	.07	.02	.01
Education	-.13**	-.14**	.00	.00
Awareness	-.02	-.01	.21**	.21***
Prior experience	.15**	.15**	.10	.10
Visits to a doctor	-.07	-.07	.04	.04
RISP components				
Risk Judgment	-.15**	-.12*	-.12*	-.11*
Optimistic Feelings	.29***	.28***	.27***	.27***
Negative Affects	-.15**	-.15**	-.03	-.03
Current knowledge	.03	.02	-.02	-.03
Sufficiency threshold	-.01	-.02	.02	.02
Informational Subjective Norms	.01	.00	.06	.05
Trust in Doctors	.21***	.23***	-.09	-.08
Information Gathering Capacity	.07	.06	-.08	-.08
Systematic Processing	.11*	--	.04	--
Heuristic Processing	--	-.09	--	-.10
Belief-based Attitudes	--	--	.19**	.19**
Multiple R	.58***	.58***	.56***	.56***
Adjusted R ²	.30	.30	.27	.28
ANOVA	F _{17,300} = 9.00	F _{17,299} = 8.81	F _{18,299} = 7.48	F _{18,298} = 7.69

*Significance regression coefficients are in bold: * $p \leq .05$; ** $p \leq .01$; *** $p \leq .001$.

The first research question sought to explore relationships among respondents' negative and positive emotions, belief-based attitudes, and intent to participate in clinical trials. After controlling for other preceding RISP variables, significant relationships were identified between both positive and negative emotions and cancer patients' attitudes toward clinical trials. Only positive emotions were significantly related to behavioral intentions, however. That is, respondents who reported feeling optimistic when thinking about clinical trials also had more positive attitudes toward clinical trials and said they were more likely to participate in a future trial. In comparison, respondents who felt negative emotions such as anger, worry, and anxiety when thinking about clinical trials were less likely to hold positive attitudes toward participation. These negative emotions did not impact on behavioral intentions when positive attitudes were included in the regression model.

The second research question asked about the relationships among other RISP components, belief-based attitudes, and intent to participate in clinical trials. Other RISP variables that significantly related to dependent variables included risk judgment and trust in doctors. Specifically, cancer patients who perceived greater risks in clinical trials also reported fewer positive attitudes and less intention to participate in a future trial. Those who trusted their doctors, however, were more likely to hold positive attitudes toward clinical trials but not necessarily more likely to participate in the future.

The third research question sought to examine the relationships among demographic variables, individual characteristics, belief-based attitudes, and intent to participate in clinical trials. Regarding individual characteristics, respondents who had participated in at least one previous trial were more likely to hold positive attitudes toward clinical trials. Those with higher education, however, were less likely to have positive attitudes toward clinical trials. Nonetheless, cancer patients who had heard

more about clinical trial opportunities reported stronger intentions to participate in a future trial. No other demographic or control variable had a significant relationship with the dependent variables. Overall, these regression models explained about one third of the variances in the two dependent variables.

Discussion

This chapter focused on how the outcome variables of the RISP model, systematic and heuristic processing, would relate to two key constructs of the TPB: attitudes toward clinical trials and intentions to participate in a future trial. Other variables of the RISP model were also tested to see how they would relate to attitudes and intentions in hope of identifying important social and individual factors that might shape cancer patients' beliefs and decisions related to clinical trial participation. In particular, this chapter was primarily interested in how affective responses, both negative and positive, would impact respondents' belief-based attitudes and behavioral intentions.

Data collected from cancer patients who use the services of the LLS indicated that systematic processing of clinical trial information is significantly related with positive attitudes that cancer patients maintain toward clinical trials. Neither systematic nor heuristic processing, however, was significantly related to intentions to participate in a future trial. Nonetheless, as proposed in the TPB, positive attitudes were significantly related to behavioral intentions, even after controlling for other RISP variables. Among other variables that were examined, education, prior experience, awareness, risk judgment, affective responses, and trust in doctors also had significant relationships with the dependent variables.

In viewing the results, it is important to recall that cancer patients might have more experience with clinical trials than average awareness among general population samples. Ninety-five percent of the respondents had heard about clinical trial

opportunities and almost half had participated in at least one trial, which is a much higher proportion than previously identified among cancer patients and healthy volunteers alike. Thus, clinical trial enrollment is a topic that is highly relevant to this group of cancer patients.

These data suggest that those who have heard a great deal about clinical trial opportunities expressed greater intention for future participation. On the other hand, respondents with higher education were less likely to hold positive attitudes toward clinical trials. This comparison warrants attention because a gap seems to exist between mere awareness and deeper understanding in terms of their impacts on cancer patients' beliefs about clinical trial enrollment. Since education is often an indicator of one's ability to comprehend and integrate complex information (Viswanath & Finnegan, 1995), the negative relationship between education and positive attitudes seems to suggest that those who are more capable to access and absorb additional information about clinical trials might possess more realistic and balanced opinions about clinical trial enrollment. That is, they tend to view clinical trial enrollment as carrying disadvantages as well as advantages.

Relationships among the key variables, however, suggest a more complex picture. Taking into account the impact of different education levels, respondents who were likely to process clinical trial information in a more in-depth and thoughtful manner were also more likely to hold favorable attitudes toward participation. These results indicate that even though education might influence one's ability to gain additional information, when cancer patients are motivated to invest in more cognitive resources to process existing information, they might form opinions that could potentially be different from their initial, more skeptical impressions. These data also indicate, however, that the effects of information processing styles seem limited to the belief system. Information processing strategies showed no significant impact on

behavioral intent, especially when belief-based attitudes were part of the regression model. In fact, after the attitudes block was entered in the final regression model, the initial significant, negative relationship between heuristic processing and behavioral intention disappeared.

Similar to results from past analyses of the TPB (see Ajzen, 2004 for a review), positive attitudes toward clinical trials had significant relationships with cancer patients' intentions to participate in a future trial, even after controlling for demographic and individual characteristics, awareness, prior experience, current knowledge, information need, risk judgment, information gathering capacity, informational subjective norms, trust in doctors, and information processing strategies. These results seem to attest to the TPB's robustness in depicting relationships between belief-based attitudes and corresponding health behaviors.

With regard to the goal to assess the RISP model as an antecedent to the TPB, only systematic processing held a significant relationship with positive attitudes in this chapter. Neither processing strategy showed a significant link to behavioral intent. Since the TPB has largely informed the development of the RISP model, future theoretical explorations should seek to draw more dynamic linkages between these two frameworks.

In particular, relevant results indicate that risk judgment and affective responses had consistent, significant relationships with belief-based attitudes and behavioral intentions. These findings suggest that these variables might not only contribute to individuals' cognitive stability by exerting an influence on their information processing styles. Rather, the cognitive and affective evaluations of potential risks might have more direct impact on individuals' cognitive structure, which subsequently shape their attitudes related to a particular behavior. In this analysis, cancer patients' risk judgment and negative emotions were negatively related

to their positive attitudes toward participation, while optimistic feelings had significant, positive relationship with both attitudes and behavioral intentions. These results seem intuitive, but they also bear important practical implications in regards to how to communicate effectively about the risks and benefits involved in cancer clinical trials. Specifically, when we decrease the amount of complex risk information in a health campaign to help cancer patients deal with the uncertainties involved in clinical trials, or simply frame risk in a more positive tone to reduce negative feelings, are we potentially encouraging false hope or pushing cancer patients into premature decisions to participate in a clinical trial? If so, is this increase in positive emotions associated with clinical trial enrollment necessarily an undesirable consequence? Past research has found that even unrealistic optimism might have positive impact on cancer patients' ability to cope with a detrimental disease and maintain physical and psychological well-being (Taylor et al., 2000). Therefore, health communicators need to fully consider and carefully balance possible emotional responses and ethical implications that messages about clinical trial enrollment might generate.

On a related note, the more consistent influence of optimistic feelings on respondents' positive attitudes and behavioral intentions seems to support the broaden-and-build theory of positive emotions (Fredrickson, 2001). In particular, the broadening hypothesis of this theory argues that positive emotions could "widen the array of thoughts and actions that come to mind" (p. 221). Even though this chapter did not artificially induce specific positive or negative emotions, the level of optimistic feelings that the respondents reported, either due to predispositions or priming effects, seem to lead to greater openness and willingness to consider clinical trial participation as an alternative form of treatment. Fredrickson (2005) has also argued that positive emotions could function as "efficient antidotes" that undo the lingering effects of negative emotions. We found that optimistic feelings preceded the other three negative

emotions in the survey, which might have made this undoing effect even stronger. Again, since these comparisons between positive and negative emotions are based on self-report data, future studies should investigate these conjectures with greater precision.

In regards to the relationship between trust in doctors and positive attitudes toward clinical trials, the unique characteristics of the patient sample might have largely shaped this finding. Even though there is evidence showing that primary care physicians do not always encourage and sometimes even dissuade their patients from participating in clinical trials (Battaglia et al., 2006), for this group of cancer patients, clinical trials might have been a frequent discussion topic during their interactions with their doctors. The number of visits they have paid their doctors in the previous 12 months also implies that most of them have fairly frequent interactions with their doctors. The sense of trust in doctors, therefore, might root in a broader sense of trust in the health system and in medical sciences. Thus, it is not surprising that a trusting doctor-patient relationship would be positively related to more positive attitudes toward clinical trials in general. However, since trust in doctors did not show a significant relationship with behavioral intentions when positive attitudes were included in the regression analysis, these respondents seemed to base their participation decisions more on their own attitudes.

These patients were also recruited from a list of users of the services of the LLS, which also actively seeks to publicize clinical trial opportunities among its user base. Since a large proportion of the respondents already have substantive knowledge and experiences with clinical trials, the fundamental assumptions behind the RISP model might not have suited this study context very well because cancer patients' motivations for information seeking and processing, as well as the actual behavior of participation, are less likely driven by a perceived mental need for more information.

As results indicate, risk judgment and emotional responses primarily influenced these respondents' attitudes toward clinical trial enrollment and their subsequent behavioral intentions. Therefore, when self-relevancy and familiarity are both preexisting conditions related to a risky situation, the RISP model might have much more limited applicability as compared to the TPB.

In viewing the results, it is important to point out study limitations. The key independent variables, the systematic and heuristic processing scales, had rather low reliability scores, which might have caused a lack of findings between these two scales and the dependent variables. Earlier studies have highlighted the importance of diversifying measurement strategies for these concepts (Schemer et al., 2008). Future research should continue to explore these alternative measures, especially the ones that might apply better to this context of health decision making. Due to the an effort to keep the telephone survey as brief as possible, several key constructs of the RISP model, such as informational subjective norms and optimistic feelings, as well as key dependent variable, behavioral intention, were measured with one question. Future research should also build up these single-item measures. Finally, interpretations based on these findings have limited external validity to a non-cancer population or to cancer patients that are not linked in with patient advocacy groups, such as the LLS.

Chapter Conclusion

In conclusion, even though most dependent variables of the RISP model did not have significant relationships with these respondents' belief-based attitudes and behavioral intentions related to clinical trials, this analysis did observe a strong impact of risk judgment and affective responses on these variables. Trust in doctors also had positive relationships with cancer patients' attitudes toward clinical trial enrollment. In addition, this chapter provided further evidence in support of the TPB proposition that attitudes toward a particular behavior will lead to corresponding behavioral intentions.

Together, these results suggest that communication about clinical trial enrollment should move beyond simply increasing awareness toward giving greater attention to cancer patients' cognitive and affective evaluations of potential risks involved in the research process. Following these two chapters that examined prospective healthy volunteers' communication behaviors and cancer patients' enrollment decisions separately, the next chapter offers another comparative investigation across the two samples. Specifically, this comparison will link relevant communication behaviors together with subsequent decision making related to clinical trial enrollment. Data from the national sample and LLS sample will be compared based on a variety of key parameters that past research has identified as having strong influence on individuals' decisions about clinical trial participation.

CHAPTER 6

COMPARING CLINICAL TRIAL ENROLLMENT DECISIONS OF CANCER PATIENTS AND PROSPECTIVE HEALTHY VOLUNTEERS – THOUGHTS, FEELINGS, OR SOCIAL INFLUENCE?

Introduction

Following the general assumptions of this research project, effective communication activities are viewed as necessary steps toward informed decision making. This final empirical chapter, therefore, extends the RISP model to explore the relative impact of various cognitive and affective processes on individuals' decisions to enroll in a future trial. Compared to other forms of decision making, health decisions are often more complex because individuals' physical or psychological well-being is at stake. Within the decision making literature, a vast amount of evidence shows that individuals are often subject to common fallacies in their reasoning (Kahneman, Slovic, & Tversky, 1982; Tversky & Kahneman, 1974). On the other hand, unconscious "deliberation-without-attention" could at times lead to superior decisions for complex problems (Dijksterhuis et al., 2006). Health care experts, therefore, have increasingly argued that the "best" health decision often depends on a given patient's personal preferences (Nelson, Han, Fagerlin, Stefanek, & Ubel, 2007). These personal preferences, in general, involve an effective information exchange between doctors and patients, a good interpersonal relationship, and involvement in the process of decision making (for a review, see Krupat & Irish, 2007).

Ryan and Sysko (2007) pointed out that U.S. patients tend to have a preference for active involvement in medical decision making because the endeavor to reduce "power distance" is intrinsic to the American culture. Empirical work also supported this argument (Degner et al., 1997; Harris, 1998). Given the greater relevancy to their personal lives, cancer patients and their families are likely to differ from healthy individuals when they make treatment decisions. Therefore, in this chapter, I will

report findings in regard to the relative impact of cognitive processing, affective responses, and social influences on attitudes and enrollment decisions among cancer patients and their families, as compared to the sample of prospective healthy volunteers. Previous chapters first examined general information seeking patterns among prospective healthy volunteers and cancer patients in the two comparable samples. Then, cancer patients' and healthy respondents' motivations for higher-level information processing and behavioral intentions related to clinical trial participation were studied. This chapter, using data from both samples, will provide the most robust evidence that speaks to the overall ethical and practical implications of this research project.

Decision Making related to Clinical Trial Participation

Existing literature on decision making related to clinical trial participation seems to suggest an interesting paradox with regard to how prospective participants deal with clinical trial information. Some researchers have argued that detailed information enabled patients to understand and participate in treatment decisions, which improved their attitudes and knowledge about clinical trials (Davis, Nealon, & Stone, 1993; Jensen, Madsen, Andersen, & Rose, 1993). Other studies, however, found that patients who refused clinical trial entry tended to be more independent decision-makers (Ellis, 2000; Llewellyn-Thomas, McGreal, Thiel, Fine, & Erlichman, 1991; Mancini et al., 2007), which suggested that greater attentiveness toward clinical trial information might not necessarily lead to the decision for participation. A preliminary project related to the current chapter also found that individuals' willingness to discuss about clinical trial opportunities mediated the relationship between their intent to participate in a future trial and the perception that their physicians treated them in a fair manner during the interactions (McComas et al., forthcoming).

Therefore, the intent to enroll in a clinical trial seems based on more than an understanding and comprehension of clinical trial information. Other factors, such as general attitudes toward clinical trials, might also contribute to this decision making processes. In fact, focusing on treatment choices, recent investigations have suggested that patients' medical decisions are often based on general attitudes, beliefs, and values (Cameron, Leventhal, & Levanthal, 1995; Trauth, Musa, Siminoff, Jewell, & Ricci, 2000), whereas physicians' decisions are usually based on symptoms and diagnosis (Barry, Fowler, Mulley, Henderson, & Weinberg, 1995). On a related note, past research has also associated the decision to participate in a clinical trial with dispositions and personality traits such as social anxiety (Almeida et al., 2008), treatment-specific optimism (Cohen et al., 2001), and self-protectiveness (Schain, 1994).

From a conceptual front end, health psychologists have applied several different approaches to examine medical decision making among cancer patients, some of which are directly applicable to clinical trials because both decision processes require the devotion of similar cognitive and affective resources. One of these approaches focuses on patients' internal cognitive processing of medical information (Miller, Shoda, & Hurley, 1996; Petersen et al., 2001). Both social learning theory and dual-processing models have guided research in this domain. In general, based on social learning theory, researchers have found that cancer patients cope with aversive health information to varying degrees based on the approach or avoidance strategies they adopt (Miller, 1989).

Studies informed by dual-processing models, on the other hand, have presented mixed evidence. One line of research has shown decision making strategies that are based on effortful information processing to relate to effective coping with cancer (Petersen et al., 2001). Other studies specifically related to clinical trials, however,

have found that breast cancer patients' decisions to enter a trial were associated with lower levels of information processing (Curbow et al., 2006). Therefore, it seems critical to examine whether the intent to enroll in a clinical trial mainly results from active decision making based on careful evaluation of clinical trial information, or whether it implies a passivity to hand over decision making to physicians and other medical researchers. The two samples in this chapter offer an opportunity to test whether comparable factors contribute to this intent among healthy respondents and cancer patients.

Past research hints at some aspects of this problem. For instance, Sharma et al. (2001) found that clinical trial patients were significantly more likely than other patients to be involved in treatment decisions, which seems to suggest that they assume a more active participating role. However, clinical trial participants might take part in the decision making process for other reasons as well. Several studies have shown that rather than a role in clinical decision-making, cancer patients appeared to desire information to satisfy "psychological autonomy" related to increased knowledge (Cox, 2002; Sutherland, Llewellyn-Thomas, Lockwood, & Till, 1989). The motivations to maintain physical and psychological well-being (such as optimism) also drive cancer patients to engage in the communication and decision-making process with their physicians (Nurgat et al., 2005; Thorne, Hislop, Armstrong, & Oglov, 2008). In fact, when evaluating the risks and benefits of phase II cancer clinical trials, institutional review board members estimated that similar to physical and therapeutic treatment, the psychological empowerment of hope also benefited patients (van Lujin, Aaronson, Keus, & Musschenga, 2006). Therefore, besides cognitive processing of clinical trial information, psychological and emotional factors might also precede individuals' enrollment decisions.

More importantly, these cognitive and affective processes might work together

to influence decision making related to clinical trial participation. In particular, Tiedens and Linton (2001) have shown that emotions characterized by certainty appraisals promote heuristic processing, whereas emotions characterized by uncertainty appraisals result in systematic processing. Based on results from their experiments, emotions associated with feeling uncertain about an outcome (regardless of its valence), such as worry and surprise, led to more systematic processing of relevant information. Given the nature of clinical studies, affects related to clinical trial participation are often linked to greater uncertainty appraisals. For instance, as two emotions most frequently identified among clinical trial participants (Abraham et al., 2006; Catania et al., 2008; Madsen et al., 2002; Meropol et al., 2007), anxiety and fear both scored low on certainty appraisal scales (Frijda, Kuipers, & ter Schure, 1989). Therefore, it is also possible that emotions associated with the idea of clinical trial participation might lead to more systematic processing of clinical trial information, which in turn, contributes to enrollment decisions.

Both the risk-as-value model (Finucane & Holup, 2006) and the affect-as-information proposition (Schwarz & Clore, 1988) support these conjectures. Since randomization and clinical equipoise are fundamental ideas behind all clinical trials, risk assessment is likely an intrinsic part of the decision making process related to clinical trial participation. As Finucane and Holup suggested, a combination of affective and analytic evaluations of risk information would assure more efficient and sound judgment. Similarly, evidence from a series of studies that Schwartz and Clore conducted also indicated that affective states could serve informative functions, such as providing judgment heuristics for individuals facing complex decisions so that they could “compute it in a piecemeal fashion.” Therefore, to examine decision making related to clinical trial participation, it is vital to take into account both the impact of cognitive evaluation of clinical trial information, as well as the influence of affective

assessment of the situation.

On a related note, upon entering a health care consumer paradigm where individual patients are potentially independent decision makers who could benefit from the large amount of available public information (Sharf & Street, 1997), decision making related to clinical trial participation is likely a communicative process that involves more actors than physicians and patients. Gordon and Daugherty (2001) found that cancer patients did not regard referring physicians as key providers of information but specified that their family members had influenced them the most to enter a trial. Other studies have also identified family pressure as a driving force behind cancer patients' decisions to enroll in a trial, together with trust in physicians and the hope to receive therapeutic benefits (Agrawal et al., 2006; Almeida et al., 2008; Daugherty et al., 1995). Since the decision to enter a trial will not only change treatment regimens for individual patients but also influence the coping strategies that patients and their families adopt, normative influences from individuals' immediate social environment could also play a role in their decision making process.

To examine the issues reviewed above within a sound theoretical framework, this chapter will continue to test linkages between the RISP model and the TPB. Specifically, this chapter will investigate the relationships among information processing strategies, affective responses, normative beliefs, attitudes toward clinical trials, and behavioral intentions. Previous chapters have generated some evidence in support of a more cohesive framework informed by the RISP model and the TPB. This chapter, using structural equation modeling for multiple group comparison, will reveal similarities and differences in the factors that work together to shape enrollment decisions among prospective volunteers and cancer patients and their family members. Rather than providing rationale for research questions and hypotheses that previous chapters have stated to some extent, key elements of the RISP model and the TPB will

involve the following:

Cognitive Processing Strategies. Based on Eagly and Chaiken's HSM, the RISP model describes dual forms of information processing strategies. As cognitive misers, most people employ the less effortful yet more economic heuristic strategy to process information unless motivated by a need to gain greater judgment confidence to engage in the more effortful and elaborate type of systematic processing. In their seminal work and subsequent empirical tests, Griffin and his fellow researchers suggested that higher level of information processing contributes to more stable and consistent attitudinal positions and subsequently, lead to the intention to perform a preventive behavior (Griffin et al., 1999; Griffin et al., 2002). Therefore, focusing on attitudes based on behavioral beliefs and behavioral intentions adopted from the TPB, this chapter hypothesizes that:

H1: Systematic processing will be positively related to positive attitudes toward clinical trial participation.

H2: Heuristic processing will be negatively related to positive attitudes toward clinical trial participation.

Affective Responses. Developed for risk communication, the RISP model differs from other mental processing models because it recognizes that affective evaluations of a risk issue would influence communication behaviors such as information seeking and processing. However, based on recent theoretical development and empirical evidence (Griffin et al., 2008; Huurne et al., forthcoming), the original positioning of affective responses in the RISP model seems outdated. Besides the direct relationships between affective response and information processing observed in recent studies (Griffin et al., 2008), as Griffin et al. (1999) posited, affective responses might also have direct influence on individuals' behavioral intentions. Therefore, this chapter investigates whether negative and positive emotions

associated with clinical trial participation relate to information processing strategies, attitudes and behavioral intentions. Specifically:

R1: How do negative emotions relate to systematic and heuristic processing, attitudes and behavioral intentions?

R2: How do positive emotions relate to systematic and heuristic processing, attitudes and behavioral intentions?

Normative Beliefs. The RISP model adopted the original TPB concept of normative beliefs and conceptualized it as informational subjective norms that work together with other components of the model to motivate systematic processing of relevant information. Similar to affective responses, recent empirical tests in a variety of research contexts have shown informational subjective norms to have more direct influence on information processing (Griffin et al. 2008; Kahlor et al., 2006). Therefore, this chapter examines normative beliefs' direct effects on information processing, as well as its direct and indirect effects on behavioral intentions, which lead to the next set of hypotheses:

H3: Normative beliefs will be positively related to systematic processing (H3a), negatively related to heuristic processing (H3b), and positively related to behavioral intentions (H3c).

Lastly, following TPB's theoretical proposition, the last hypothesis is focused on the relationship between attitudes and behavioral intentions:

H4: Belief-based attitudes will be positively related to behavioral intentions related to clinical trial participation.

Method

Data

Viewing these two datasets together, respondents in the national sample appeared to be slightly younger ($M_{NAT} = 49.83$, $SD_{NAT} = 16.04$; $M_{LLS} = 53.99$, $SD_{LLS} =$

12.00; $t_{[985]} = 4.61, p < .001$), with less education ($M_{NAT} = 4.96, SD_{NAT} = 1.69$; $M_{LLS} = 5.53, SD_{LLS} = 1.41$; $t_{[995]} = 5.87, p < .001$, ranging from eighth grade or less [coded as 1] to post-graduate training [coded as 7]), and less income ($M_{NAT} = 54,100, SD_{NAT} = 24,100$; $M_{LLS} = 59,500, SD_{LLS} = 21,160$; $t_{[917]} = 3.66, p < .001$, ranging from less than \$10,000 to \$150,000 or more). Both samples were predominantly White, but the LLS sample had more female respondents ($\chi^2_{[1]} = 5.83, p < .05$). Compared to the 2006 American Community Survey (U.S. Census Bureau, 2007), the national sample seemed to have slightly over represented individuals with higher income, but the other parameters were quite similar.

Measurement

Measures for key variables were adopted from past analyses based on the RISP model (Griffin et al., 2008; Griffin et al., 2002). As with the previous chapters, the specific questionnaires appear in Appendix 2A and 2B, whereas the particular items used to measure each variable are indicated below in footnotes.

Cognitive Processing Strategies. Six items measured respondents' cognitive processing strategies.²⁰ Past analyses have primarily used exploratory factor analysis to examine the construct validity of these six items in measuring systematic and heuristic processing. The current chapter, following the recommendation of Schemer et al. (2008), tested construct validity through a confirmatory factor analysis. Overall, respondents in the LLS sample scored higher for items intended to measure systematic processing, and lower for those intended to measure heuristic processing. Mean comparisons through independent samples t-test found significant differences between these two samples in all these measures.

Affective Responses. Respondents indicated on 10-point scales how optimistic,

²⁰ Items 16 & 18-22 in the questionnaire

afraid, worried, and anxious they felt when thinking about enrolling in a clinical trial. LLS respondents gave higher ratings on measures of optimism ($t_{[980]} = 12.78, p < .001$) and anxiety ($t_{[986]} = 3.24, p < .001$), but their scores for fear and worry were not significantly different from respondents in the national sample.

Normative Beliefs. Consistent with past research, respondents also indicated whether they believed that people who were important to them would want them to stay informed about enrolling in a clinical trial.²¹ Mean comparison test indicated that LLS respondents sensed greater normative influence in general ($t_{[982]} = 11.33, p < .001$).

Belief-based attitudes. Respondents indicated their agreement with five statements describing beliefs associated with clinical trial enrollment ranging from financial concerns to altruistic reasons.²² Past research has identified these beliefs among cancer patients facing the decision to enroll in a clinical trial (Comis et al., 2003; Schain, 1994). These behavioral beliefs and their corresponding evaluations²³ were linked together to measure belief-based attitudes (Ajzen, 1988). In general, LLS respondents indicated more positive attitudes toward clinical trial participation.²⁴

Behavioral intention. Two items measured respondents' general behavioral intentions related to clinical trial enrollment, based on their own willingness to enroll in a trial and the likelihood that they would encourage someone they know to enroll.

²¹ Item 11 in the questionnaire

²² Items 29-33 in the questionnaire

²³ Items 34-38 in the questionnaire

²⁴ Similar to the analysis in Chapter 5 where optimistic feelings were examined along with positive attitudes, assuring discriminant validity, inter-variable correlations (average $r = .35$, ranging from .24 to .40) was lower than correlations among measures of positive attitudes (average $r = .41$, ranging from .27 to .80).

²⁵Again, LLS respondents scored higher on both items, indicating higher intentions for clinical trial enrollment.

Analysis

This chapter used the LISREL 8.80 structural equation modeling (SEM) program for data analysis. LISREL provides tests of the adequacy of the entire model, simultaneous estimation of all structural coefficients, and tests of statistical significance for all coefficients. To test the overall model, we followed a two-step procedure recommended by Kline (2005). Through confirmatory factor analysis, a measurement model was first specified and refined, based on which estimation of the structural model was completed. The overall goal was to find a parsimonious structural model that explained the data reasonably well (Kline, p. 217). This technique also enabled this analysis to assess the reliability and validity of these latent constructs with greater precision (Schemer et al., 2008). In order to compare relationships among key variables, a structural equation model was analyzed across the two samples. According to Kline, the main question addressed in a multiple-sample SEM is whether values of model parameters vary across groups, which provides another tool to examine whether group membership moderates the relations specified in the model. In other words, the goal of this analysis was to estimate the same model within these two samples and then compare the unstandardized solutions across the samples.

As Jöreskog & Sörbom (1996b) pointed out, in a multi-sample analysis, the χ^2 goodness-of-fit statistic is a measure of fit of all models in all groups, where a nonsignificant value indicates good fit. Because χ^2 has been shown to be sensitive to sample size (Bollen, 1989), the χ^2/df ratio is also reported, where a value less than five

²⁵ Items 3 & 4 in the questionnaire

indicates a good fit (Klein, p. 137). The root mean square error of approximation (RMSEA) and the Comparative Fit Index (CFI), the Goodness-of-Fit Index (GFI), and the Adjusted Goodness-of-Fit Index (AGFI) are also reported, which demonstrate how well the specified model accounts for the data. RMSEA values less than .05 typically indicate good fit. For CFI, GFI and AGFI (values ranging from .00 to 1.00), .90 and above is generally considered to represent good fit. Regression coefficients for the hypothesized structural relations are reported along with their statistical significance. A probability level of $p < .05$ was used as the base level of statistical significance.

Results

The effective sample size for data analysis with list-wise deletion was 886. Through the imputation function in PRELIS, 61 more cases were added, which resulted in a final effective sample size of 947. Imputation in PRELIS substitutes the missing value of a case with a real value obtained from another case that has a similar response pattern over a set of matching variables (Jöreskog & Sörbom, 1996a, p. 153). Table 6.1 and Table 6.2 present descriptive statistics of the two samples, including correlation coefficients in the upper triangle of the matrix, covariance coefficients in the lower triangle, and variances along the diagonal. The zero-order correlation matrix was generated in SPSS17.0 prior to data imputation using the raw data; the covariance matrix was generated in the PRELIS package of LISREL 8.80 after data imputation. The covariance matrix was used for SEM tests (Jöreskog & Sörbom, 1996b). To reduce potential measurement error for those variables that were measured with a single item, this analysis assumed an arbitrary reliability value of .85, which was equivalent to an error variance of .15 times the variance of the observed variable (Jöreskog & Sörbom, 1996b, p. 37).

Table 6.1
Descriptive statistics (national sample)

Key Variables	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
1. TPB1	23.64	.77**	.49**	.23**	.24**	.38**	.36**	.26**	-.11*	-.31**	-.15**	.34*	.30**	.14**	.36**	.01	-.03	.03
2. TPB2	90.54	20.75	.55**	.28**	.27**	.32**	.34**	.20**	-.13**	-.28**	-.16**	.29**	.30**	.10**	.28**	-.03	-.04	.02
3. TPB3	56.23	51.70	22.76	.25**	.30**	.30**	.33**	.21**	-.08	-.29**	-.11*	.27**	.20**	.12**	.27**	-.07	-.05	-.01
4. TPB4	12.90	14.20	11.13	22.01	.38**	.19**	.16**	.10*	-.09	-.14**	-.14**	.15**	.15**	.10*	.17**	-.19**	-.18**	-.08
5. TPB5	6.69	6.20	6.39	4.77	21.08	.30**	.21**	.14**	-.10*	-.14**	-.15**	.25**	.12**	.15**	.26*	-.13**	-.15**	-.10*
6. BHINTself	5.13	3.58	3.11	.98	.81	1.61	.62**	.28**	-.14**	-.36**	-.16**	.37**	.22**	.17**	.41**	.01	-.05	.06
7. BHINTother	4.86	4.02	3.90	.90	.61	.78	1.54	.25**	-.08	-.33**	-.14**	.28**	.24**	.13**	.40**	-.02	-.04	.04
8. NORM	3.90	2.31	2.38	.65	.44	.33	.31	1.17	-.01	-.19**	-.09*	.27**	.17**	.10*	.23**	.00	-.04	-.02
9. HEU1	-1.55	-1.36	-.89	-.46	-.25	-.13	-.09	-.02	1.22	.19**	.22**	-.07	-.06	-.03	-.12*	.01	.03	-.04
10. HEU2	-3.25	-2.48	-2.29	-.55	-.27	-.33	-.33	-.19	.17	1.25	.28**	-.42**	-.25**	-.27**	-.32**	-.03	-.01	-.02
11. HEU3	-.86	-1.01	-.64	-.53	-.27	-.09	-.09	-.07	.17	.14	1.07	-.21**	-.15**	-.08	-.16**	-.02	-.02	.00
12. SYS1	4.06	3.10	2.73	.90	.65	.40	.31	.31	-.10	-.37	-.12	.89	.39**	.24**	.28**	.00	-.03	.02
13. SYS2	5.07	4.25	2.67	1.03	.36	.26	.25	.22	-.15	-.27	-.13	.56	.79	.08**	.22**	.06	.02	.07
14. SYS3	1.59	.96	1.03	.45	.30	.16	.15	.11	.00	-.17	-.03	.22	.10	.95	.19**	-.00	-.03	.02
15. OPTIMISM	30.57	20.44	18.39	5.13	4.21	2.94	2.84	1.73	-.93	-1.18	-.64	1.99	1.90	1.13	7.19	.14**	.06	.10*
16. FEAR	-3.77	-5.58	-9.89	-10.50	-3.90	-.55	-.77	-.18	-.02	-.04	.00	-.42	.40	-.08	9.01	9.36	.84**	.64**
17. WORRY	-4.36	-3.72	-3.91	-5.27	-2.52	-.51	-.42	-.35	.12	-.12	-.06	-.34	.09	-.05	1.84	47.37	9.62	.71**
18. ANXIETY	-.06	-.51	-1.40	-2.03	-1.58	.17	.16	-.18	-.19	-.12	.00	-.04	.48	.15	3.69	34.84	20.93	9.48
<i>M</i>	14.85	15.68	14.07	11.02	9.85	3.03	3.30	3.15	2.88	3.10	2.73	3.82	4.05	3.32	4.95	5.41	5.47	5.22
<i>SD</i>	4.86	4.56	4.77	4.69	4.59	1.27	1.24	1.08	1.10	1.12	1.03	.94	.89	.97	2.68	3.06	3.10	3.08

*Pearson correlation coefficients are provided in the upper triangle of the matrix, variances are located on the diagonal, and covariances are reported in the lower triangle.

Significance key: * $p \leq .05$; ** $p \leq .01$.

Table 6.2
Descriptive statistics (LLS sample)

Key Variables	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
1. TPB1	27.72	.79**	.44**	.21**	.25**	.27**	.25**	.14**	-.08	-.07	-.02	.13**	.08	.11*	.30**	-.19**	-.18**	-.14**
2. TPB2	34.72	24.39	.52**	.22**	.30**	.30**	.29**	.15**	-.06	-.10*	.03	.16**	.10*	.12**	.35**	-.10*	-.12**	-.08
3. TPB3	8.92	22.97	29.11	.26**	.31**	.30**	.35**	.18**	.00	-.17**	-.04	.11*	.07	.11*	.39**	-.18**	-.20**	-.16**
4. TPB4	1.48	3.73	1.87	25.67	.32**	.18**	.16**	.05	-.10*	-.16**	-.02	.10*	-.06	.04	.19**	-.09*	-.11*	-.14**
5. TPB5	3.64	9.65	4.30	1.64	24.95	.20**	.22**	.02	-.01	-.07	-.00	-.06	.02	.13**	.30**	-.20**	-.22**	-.20**
6. BHINTself	1.55	3.63	1.69	.36	.77	.80	.57**	.13**	-.10*	-.18**	-.03	.08	.00	.12**	.39**	-.20**	-.23**	-.20**
7. BHINTother	1.49	3.51	1.91	.36	.82	.81	.82	.11*	-.03	-.12**	.03	.06	-.04	.04	.40**	-.14**	-.16**	-.12**
8. NORM	.94	2.18	1.20	.12	.10	.25	.19	1.11	-.11*	-.23**	-.08	.15**	.07	.24**	.17**	.05	.04	.02
9. HEU1	-.31	-.72	-.05	-.16	.02	-.10	-.05	-.15	1.37	.29**	.17**	-.22**	-.04	-.20**	-.08	-.04	-.04	-.01
10. HEU2	-.28	-.82	-.62	-.21	-.14	-.14	-.10	-.24	.21	1.03	.14**	-.37**	-.11*	-.26**	-.09*	-.04	-.00	.02
11. HEU3	-.13	-.09	-.23	-.03	-.04	-.04	.01	-.08	.12	.09	1.11	-.06	.03	-.10*	.00	.05	.05	.05
12. SYS1	.87	2.45	.83	.25	.24	.10	.08	.36	-.27	-.41	-.08	.65	.26**	.22**	.03	.09*	.08	.02
13. SYS2	.58	1.92	.48	-.10	.14	-.04	-.11	.23	-.08	-.15	.01	.68	.74	.07	-.05	.13**	.13**	.19**
14. SYS3	.59	1.39	.53	.06	.51	.14	.08	.32	-.18	-.22	-.07	.38	.17	.90	.09*	.03	-.00	.01
15. OPTIMISM	7.74	20.64	9.49	1.64	5.34	2.69	2.60	1.31	-.40	-.41	-.01	.11	-.36	.43	4.38	-.16**	-.19**	-.20**
16. FEAR	-5.87	-8.54	-5.44	-.81	-4.18	-1.76	-1.41	.29	-.27	-.09	.20	.51	.99	.11	-6.32	8.72	.88**	.79**
17. WORRY	-4.08	-6.83	-4.11	-.66	-3.18	-1.38	-1.08	.22	-.22	.05	.17	.31	.70	-.05	-5.52	24.39	8.81	.84**
18. ANXIETY	-3.10	-4.92	-3.38	-.92	-2.92	-1.11	-.81	.11	-.09	.10	.14	.02	1.02	.09	-5.29	22.26	16.53	8.50
<i>M</i>	18.03	18.57	16.47	13.14	12.59	4.25	4.27	3.92	2.54	2.32	2.52	4.25	4.26	3.64	6.91	5.55	5.45	5.84
<i>SD</i>	5.27	4.94	5.40	5.07	5.00	.90	.91	1.05	1.17	1.01	1.06	.81	.86	.95	2.09	2.95	2.97	2.92

*Pearson correlation coefficients are provided in the upper triangle of the matrix, variances are located on the diagonal, and covariances are reported in the lower triangle.

Significance key: * $p \leq .05$; ** $p \leq .01$.

The initial CFA model, simultaneously fitted to covariance matrices for the national sample and the LLS sample, was rejected because the assumed invariance across all model parameters was not supported ($\chi^2 = 1903.24$, $df = 280$, $\chi^2/df = 6.80$, p

< .05, RMSEA = .111, CFI = .75). The revised CFA model assumed different error variances across the two groups, which improved model fit ($\chi^2 = 1009.37$, $df = 271$, $\chi^2/df = 3.72$, $p < .05$, RMSEA = .076, CFI = .91). The next CFA model allowed factor loadings to be different for variables that measured belief-based attitudes and negative emotions, which led to a much more improved measurement model ($\chi^2 = 660.49$, $df = 265$, $\chi^2/df = 2.49$, $p < .05$, RMSEA = .056, CFI = .95), but the RMSEA was still above the cutoff point of .05. The last steps of revision allowed several error covariances to be different across the groups, including attitude measures and the error covariance of fear and optimism, which resulted in the final CFA model ($\chi^2 = 570.47$, $df = 261$, $\chi^2/df = 2.19$, $p < .05$, RMSEA = .050, CFI = .96). Since these observed variables were designed to measure similar constructs, these revisions were justified conceptually.

Based on the refined CFA model, a structural model was specified. Results for the overall model fit are presented in Table 6.3.

Table 6.3
Summary of fit indicators

Models	χ^2	df	P	χ^2/df	RMSEA	GFI	CFI
Baseline CFA model	1903.24	280	<.05	6.80	.111	.78	.75
Revised CFA model ^a	570.47	261	<.05	2.19	.050	.94	.96
Baseline conceptual model	749.87	264	<.05	2.84	.062	.91	.94
Revised model ^b	533.58	259	<.05	2.06	.047	.94	.97

*RMSEA = root mean squared error of approximation; GFI = Goodness-of-Fit Index; CFI = Comparative Fit Index.

- a. Revision from baseline CFA model to final CFA model: allow error variances and factor loadings to be different across groups; allow error terms between attitude measures and between fear and optimism to covary.
- b. Revision from baseline model to final model: allow path coefficients for key endogenous variables to be different across groups, deleted non-significant paths.

Analysis of the overall model fit along with tests of individual paths indicated that allowing regression coefficients to be estimated differently for paths leading to

key endogenous variables, attitudes and behavioral intentions, could improve model fit. After deleting non-significant paths across the two groups, the final model ($\chi^2 = 533.58$, $df = 259$, $\chi^2/df = 2.06$, $p < .05$, RMSEA = .047, CFI = .97) fit the data relatively well. Even though fixing several path coefficients to be equal could result in a slightly more parsimonious model, in order to compare across the two samples, all the path coefficients were estimated separately. Figure 6.1 shows unstandardized regression coefficients for the national sample and the LLS sample, with the latter in the parentheses.

In regards to specific research questions and hypotheses, as proposed in the first hypothesis, systematic processing was positively related to positive attitudes toward clinical trial participation in both the national sample ($\beta = .37$, $t = 4.88$, $p < .05$) and the LLS sample ($\beta = .19$, $t = 2.29$, $p < .05$). Comparing unstandardized regression coefficients, this relationship was stronger in the national sample, as shown in Figure 6.1. Therefore, H1 was supported in both samples. In addition, taking into account the indirect effects through attitudes, systematic processing also seemed to have greater total effects on behavioral intentions in the national sample than in the LLS sample (unstandardized total effects: .42_{NAT} vs .10_{LLS}; standardized total effects: .29_{NAT} vs .07_{LLS}). Heuristic processing, on the other hand, was only significantly related to attitudes in the national sample ($\beta = -.14$, $t = -2.10$, $p < .05$) and thus, had marginally significant indirect effects on behavioral intentions (unstandardized total effects: -.33_{NAT}; standardized total effects: -.11_{NAT}). Therefore, H2 was supported in the national sample but not in the LLS sample.

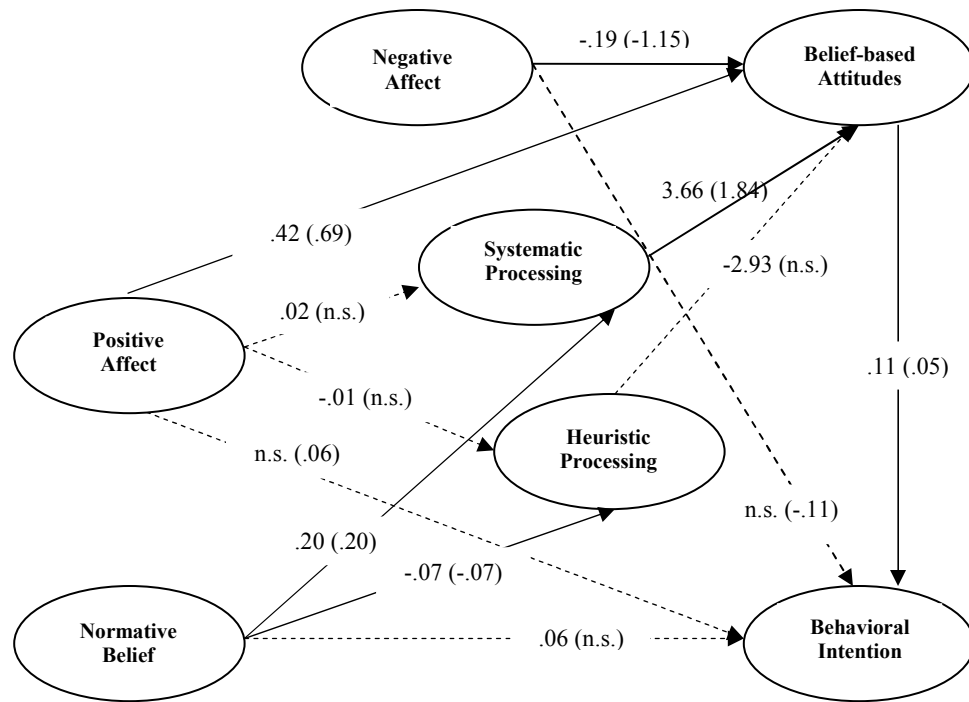


Figure 6.1

Results for the conceptual model with statistically significant paths

*Unstandardized solution from structural equation modeling (SEM) analysis for the national sample and the LLs sample, with the latter in parentheses.

The third set of hypotheses focused on normative beliefs' relationships with information processing and behavioral intentions. In the national sample, all three hypotheses received support. Normative beliefs were positively related to systematic processing ($\beta = .35$, $t = 7.12$, $p < .05$), negatively related to heuristic processing ($\beta = -.25$, $t = -4.85$, $p < .05$), and positively related to behavioral intentions ($\beta = .07$, $t = 2.07$, $p < .05$). In the LLS sample, however, even though normative beliefs were significantly related to systematic ($\beta = .33$, $t = 5.55$, $p < .05$) and heuristic processing ($\beta = -.26$, $t = -4.22$, $p < .05$), constraining regression coefficients to be equal across the two samples results in a more parsimonious model without sacrificing model fit. Therefore, these two parameters were not estimated separately. Normative beliefs

were not significantly related to behavioral intentions in the LLS sample. Including indirect effects, normative beliefs had stronger total effects on behavioral intentions (unstandardized total effects: .17_{NAT} vs .09_{LLS}; standardized total effects: .18_{NAT} vs .12_{NAT}) and attitudes (unstandardized total effects: .94_{NAT} vs .58_{LLS}; standardized total effects: .17_{NAT} vs .10_{LLS}) in the national sample.

Lastly, the relationships between belief-based attitudes and behavioral intentions were significant in both samples, as stated in the final hypothesis. However, this relationship was stronger in the national sample ($\beta = .78, t = 9.77, p < .05$) than in the LLS sample ($\beta = .36, t = 5.17, p < .05$). Overall, in the national sample, the model explained 51% of the variance in behavioral intentions and 68% of the variance in attitudes, whereas in the LLS sample, it accounted for 50% of the variance in behavioral intentions and 49% of the variance in attitudes.

Discussion

The purpose of this chapter is to examine a theoretical linkage between the RISP model and the TPB in depicting socio-psychological factors that shape clinical trial enrollment decisions of cancer patients and their caregivers, as well as prospective healthy volunteers. Rather than testing how various RISP components explain individuals' motivations to engage in higher-level information processing, this analysis aimed at exploring what originates from these information processing strategies to shape individuals' health decisions. Therefore, following Griffin et al.'s (1999) original theoretical projection, cognitive processing strategies were juxtaposed with positive and negative emotions, as well as normative beliefs to investigate their impact on belief-based attitudes and behavioral intentions, within the TPB's overarching framework. In order to compare the relative influence of each exogenous variable on endogenous variables, the same model was specified across the two samples even though path coefficients were estimated separately when appropriate.

Through multiple-sample structural equation modeling, key findings indicate that attitudes, cognitive processing strategies, affective responses, and normative beliefs could account for about half of the variances in behavioral intentions related to clinical trial participation in both samples.

However, these two samples also differ in several key aspects. First of all, information processing strategies did not influence attitudes and behavioral intentions in the LLS sample to the same degree as in the national sample. In fact, in the LLS sample, heuristic processing was not significantly related to attitudes or behavioral intentions at all. Upon a first look, these results seem to suggest that healthy respondents are more likely to base their enrollment decisions on careful evaluations of available clinical trial information. However, since cancer patients and their caregivers are in general more knowledgeable and experienced with clinical trials, an alternative explanation could be that respondents in the national sample responded to these questions based on a general preference for more information and better comprehension when it comes to health decision making. Since respondents in the LLS sample are already, presumably, well-informed about clinical trial opportunities, too much information might actually turn them away and make them feel overwhelmed. Their responses to these questions, therefore, might express a tendency to avoid information to reduce distress, as a coping mechanism. Past studies have identified similar phenomena among cancer patients and clinical trial participants (Brashers et al., 2002; Leydon et al., 2008). Thus, compared to other predicting variables, information processing strategies did not influence their attitudes and behavioral intentions as much. Therefore, the stronger relationships between systematic processing and positive attitudes shown in the national sample might not indicate a lack of cognitive involvement among cancer patients and their caregivers when it comes to decision making related to clinical trial enrollment. Rather, these

findings suggest that among those who might not be fully aware of clinical trial opportunities, the more effortful and engaged information processing strategy might enhance their overall attitudes toward clinical trial participation and indirectly lead to greater willingness to enroll in a clinical trial.

On the contrary, affective responses played a bigger role in influencing attitudes and behavioral intentions among cancer patients and their caregivers. Together with existing evidence showing the importance of emotions in shaping people's enrollment decisions (Catania et al., 2008; Jones et al., 2006), these findings indicate that health communication efforts, especially those targeted at enhancing clinical trial enrollment, should pay close attention to patients' emotional reactions to specific messages and their interactions with physicians and other medical researchers. More importantly, positive emotions (optimistic feelings, in this case) not only had direct relationships with attitudes and behavioral intentions in the LLS sample but also had indirect effects on attitudes through systematic processing. These findings seem to support the idea that when the task is important, positive emotions not only do not deter systematic processing, as some researchers have argued (Schwarz & Bless, 1991), but could actually prompt people to invest in more cognitive resources to process relevant information more effectively, especially when the decision involves some degree of risk taking (see Isen, 1999 for a review). Additional support for this conjecture comes from social psychology studies showing optimistic beliefs about one's health as related to greater attention to risk information, especially when the information is self-relevant (Aspinwall & Brunhart, 1996). Therefore, following the assumption that clinical trial participation offers a unique case study of risk, it was not surprising that positive emotions (optimistic feelings) stood out as the most influential predicting variable in this model that investigates the direct and indirect linkages among affects, cognitive processing, attitudes, and behavioral intentions.

On the other hand, comparing the different emotions examined in this chapter, optimistic feelings had stronger total effects on attitudes and behavioral intentions than negative emotions across the two samples. Since all emotions were assessed based on self-report measures, they were most likely associated with individuals' innate dispositions. As Scheier and Carver (1992) pointed out, dispositional optimism is often associated with active, problem-focused coping and involves a more generalized expectancy (as compared to self-efficacy) toward future events that facilitates the practice of health-enhancing behaviors. Therefore, it is possible that cancer patients and their caregivers in this study are indeed more motivated by optimistic feelings associated with clinical trial enrollment when they make decisions about future participation, either in anticipation for beneficial outcomes or in an effort to maintain active control over their regimen. On a related note, both the cognitive adaptation theory (Taylor, 1983) and the broaden-and-build theories of positive emotions (see Fredrickson, 2005 for a review) suggest that positive beliefs and feelings could serve as important psychological resources that help people adapt to stressful events and protect health. Therefore, not only did optimistic feelings outperformed negative emotions in motivating systematic processing of clinical trial information, they also incited more positive attitudes toward clinical trials and a great likelihood for future participation, especially among cancer patients and their caregivers.

While most of the results confirmed existing beliefs based on theoretical proposition and empirical evidence, there were also some unexpected findings. In particular, even though normative beliefs were significantly related to information processing in both samples, they also influenced healthy respondents' enrollment decisions more than cancer patients and their caregivers. These findings seem to contradict the strong influence of cancer patients' physicians, family members and friends in shaping their decisions about clinical trial enrollment, as past research has

revealed (Albrecht et al., 2008). However, a closer examination of existing literature indicates that compliance with social norms has always acted as a critical motive among healthy prospective volunteers (Almeida et al., 2008; Pentz et al., 2002). Therefore, these results seem to suggest that it is possible to encourage greater awareness and attention to this issue among the general public by emphasizing that clinical trial participation is an altruistic act that will facilitate scientific advancement and benefit medical research.

Similarly, the relationship between belief-based attitudes and behavioral intentions was also stronger in the national sample as compared to the LLS sample. Considering this finding together with the one previously discussed, an alternative explanation might also be true. That is, rather than viewing normative beliefs and positive attitudes as less important to cancer patients and their caregivers, they might simply have generated greater influence on healthy respondents' decision making processes because cancer patients and their caregivers gave overall higher ratings on these measures. In other words, since LLS respondents generally hold positive attitudes about clinical trials and value the opinion of those who are important to them, other factors, such as affects, might seem more salient when linked together with enrollment decisions.

It is important to consider potential limitations to this study. First of all, even though error variances were specified for observed variables that assessed normative beliefs and optimistic feelings to account for possible measurement error, these two constructs need to be evaluated more precisely in future research given the predicting power they seem to possess. At the same time, consistent with previous chapters, the item used to measure normative beliefs was more information-oriented rather than participation-oriented. That is, the social expectation examined was more related to being on top of information about clinical trial enrollment, rather than actual

participation. This compromise with measurement strategy, due to model complexity in multiple-sample comparison, might also explain why normative beliefs were more consistently related to information processing across the samples, rather than behavioral intentions. Lastly, even though the exogenous variables included in the model accounted for a decent proportion of variances in the endogenous variables, several other key components of the RISP model and the TPB, such as risk judgment, efficacy, and channel beliefs, were left out. Future analysis will continue to explore other SEM techniques that will allow the addition of these important predicting variables while ensuring model convergence.

Chapter Conclusions

Key findings from this analysis suggest that to improve clinical trial enrollment, campaigns that disseminate information broadly, with a format that promotes careful evaluation of the pros and cons of participation as related to each individual, as well as an emphasis on establishing social norms might be most effective among the general public. However, to target a specific group of cancer patients and their caregivers, health interventions need to include a mechanism that monitors the emotions that these individuals associate with the processes of subject accrual, informed consent attainment, and actual trial procedure, especially when it comes to maintaining a sense of optimism without fostering unrealistic or defensive optimism. As Schwarzer (1994) pointed out, it is insufficient to suppress defensive optimism by arousing fear among the patients. Rather, health and risk communication efforts should aim at triggering the perception of optimistic self-beliefs as a “prerequisite for the adoption of instrumental precautions” (p. 177). In other words, Schwarzer argued that some sense of vulnerability is not only necessary, but also indispensable for behavioral change, when operated jointly with beliefs about positive health outcomes, instrumental actions, and appropriate coping resources. Upon similar

reasoning, some degree of uncertainty might also be a necessary condition for the adoption of communication behaviors such as information seeking and processing related to clinical trial enrollment. Based on this and previous chapters, promoting these communication behaviors, while assisted by other practices such as incorporating individuals' disposition toward risk and uncertainty, as well as their willingness to subject to social desirability, will improve the communications of clinical trial enrollment among both the general public and specific patient groups.

CHAPTER 7

OVERALL CONCLUSION AND FUTURE RESEARCH

Reflection

Following a review of the propositions and development of the RISP model, the four chapters that immediately precede this final chapter have tested the applicability of the model and its extensions in a context of health decision making, specifically related to clinical trial enrollment decisions. Overall, results from the national sample and the LLS sample, through separate analyses and comparative investigations, seem coherent in shaping up the bigger picture. Key components of the RISP model have shown significant impact on respondents' motivations for routine and non-routine information seeking, as well as systematic and heuristic processing. When the RISP model was linked together with the TPB framework, different parts of the model also exemplified varying degrees of explanatory power in belief-based attitudes and behavioral intentions. Along with the rationale presented in Chapter 2, these results indicate that viewing clinical trial enrollment as a unique case study for risk seems a reasonable strategy to deal with this health communication problem. The RISP model also seems to offer a useful framework to shape formative research for the design of communication campaigns related to clinical trial enrollment. This final chapter reflects on how results from these substantive chapters have complemented each other in approaching a tentative conclusion for this question. A comprehensive overview of these empirical findings, naturally, also sheds light on areas that future research should continue to explore.

Before elaborating on these findings in this final chapter, it is important to reiterate the main purpose of this research project, which is to explore how to improve the communications of clinical trial enrollment in order to facilitate informed decision making among cancer patients and prospective healthy volunteers. To do this, key

results from the preceding four chapters have not only offered evidence in argument for the refinement of the RISP model, but they have also suggested important strategies with which practitioners could improve the accrual of clinical trial participants to make this procedure more effective and ethical. An important caveat here is that even with the best intention, scientific findings, including those from social science research, might be exploited to profit certain interest groups or organizations. It is important, therefore, to highlight the ethical implications of results from this dissertation. Given the unique composition of the LLS respondents in this investigation, they might have mainly viewed clinical trial research as related to the improvement of cancer treatment. Respondents in the national sample, however, might have taken clinical trials as referring to a broader range of clinical studies that also include drug testing and other biomedical research. When evaluating the patterns of results in these two samples, it is important to take into consideration this important distinction in the respondents' profiles.

In addition, even though similar vocabularies were used to describe research background for this dissertation, such as the detection of the barriers that keep individuals from volunteering in clinical trials, this research effort is fundamentally different from the general forms of "recruitmentology" studies that Epstein (2007) criticized. Specifically, the underpinning issue here is to discover how to engage cancer patients and healthy respondents in the communication process, which is different from how to manipulate their penchant or foster blind trust in medical research or medical researchers. In other words, risk and health communication research aims at increasing awareness and facilitating understanding of important risk and health issues to prepare ordinary citizens to take on a participatory role in the decision making process. As a basic assumption, acquisition and comprehension of information are crucial stages to reach informed decision making. In terms of the

construction and management of risk on a societal level, this audience-based orientation might seem a bit narrow as compared to the focus on “system builders,” including actors such as policy makers and influential interest groups, as Hilgartner (1992) proposed. However, the prospect of constructing new models of trusting relationships between patients and researchers in the long term will deliver on more meaningful expectations for this research effort.

Viewing the results from individual chapters together, the most important finding arises from the comparison between the national sample and the LLS sample. In general, cognitive processing strategies had a stronger impact on attitude formation and behavioral intention among prospective healthy volunteers, whereas affective responses primarily influenced LLS respondents’ decisions about clinical trial enrollment (comparing results from Chapters 4, 5 and 6). A plausible conclusion, based on these results, could be that cancer patients and their caregivers were more likely to base their decisions on “irrational” feelings rather than thinking. However, it is important to stress that this relatively stronger relationship took shape within a unique research context. That is, as compared to respondents in the national sample, cancer patients and their caregivers in the LLS sample had more education, income, and previous experience with clinical trial enrollment. More importantly, they also reported much higher base-level awareness and knowledge with clinical trial enrollment. Thus, when questioned about preferences for information processing strategies along with emotional reactions to the idea of clinical trial participation, it is possible that emotions have taken precedence in their responses because in general, emotions could have more direct impact on risky choice behaviors. This reasoning comes in line with the “risk as feelings” hypothesis (Loewenstein et al., 2001). These authors argue that immediate emotional reactions during the decision making process could play a large role in choice behavior, independent of the outcome, resulting in

evaluations that may diverge from the desired cognitive or analytic evaluation. Therefore, a more reasonable conclusion from this comparison is that when it comes to forming decisions related to clinical trial enrollment, emotional reactions are important, but only when accompanied with sufficient information and comprehension. When existing knowledge does not suffice individuals to reach a sound judgment, cognitive processes still seem more salient in influencing their decisions.

Risk perception, albeit measured by the most generic form of risk judgment based on an estimate of probability and severity, was one of the RISP components that performed most consistently across the different chapters. An interesting finding worth noting is that even though risk judgment was positively related to routine information seeking in both samples, it was related to non-routine information seeking in opposite directions across the two samples (Chapter 3). Focusing on respondents from the national sample, Chapter 4 also identified risk judgment as indirectly related to information seeking through current knowledge. That is, risk judgment seemed to highlight a greater need for information by influencing respondents' estimate of how much they already know about clinical trial enrollment. In comparison, risk judgment was negatively related to both positive attitudes and behavioral intention among LLS respondents (Chapter 5). Viewing these findings together, perceived risk seemed to have a rather distinctive influence on respondents in these two samples. Even though it motivated prospective healthy volunteers to engage in more information seeking, this effort was embodied through routine activities such as paying attention to information in the mass media, rather than through more purposive and targeted activities such as searching for information on the internet. For cancer patients and their caregivers, perceived risk motivated information seeking from a variety of sources. Greater risk perception and increased information seeking, however, resulted in a less positive

attitude and lower intention to participate in a future trial. Thus, as Slovic (1992) pointed out, risk indeed seemed to be a concept that helped individuals to understand and cope with the prevalent uncertainties in their lives. For LLS respondents, since the risks and uncertainties related to clinical trial enrollment are more tangible and salient, perceived risk had a much more complex impact on their communication behaviors and subsequent health decisions. The seeming discrepancy in its relationships with greater information seeking and less behavioral intention also indicates that health communicators should not assume that more exposure to information automatically translates to the decision to participate. Based on findings from Chapter 3 and Chapter 5, when perceived risk is high, more information might actually correlate with less intention for clinical trial enrollment.

One of the most unique aspects of this research project involves the comparison of the motivating effects of negative and positive emotions within the context of the RISP model. Overall, optimistic feelings, representing positive emotions, had a consistent, strong impact on both forms of information seeking and information processing, as well as on attitudes and behavioral intentions across the two samples (synthesizing from Chapters 3 to 6). Negative emotions (measured as a latent construct represented by fear, worry, and anxiety) were the primary driving force behind information seeking through non-routine sources. Negative emotions also primarily influenced LLS respondents' attitudes and behavioral intentions. In general, these results indicated that as compared to negative emotions, optimistic feelings might play a more important role in motivating communication behaviors and influencing individuals' decisions related to clinical trial enrollment. Theoretically, this comparison would warrant a role for positive emotions as part of the affective response component of the RISP model. More importantly, these findings seemed to speak to the phenomena of "positivity offset" and "negativity bias" that social

psychologists have discussed in relation to the co-existence of two motivational systems (Cacioppo & Berntson, 1994). That is, the activation function of these two motivational systems tends to work in different ways. At low levels of exposure to evaluative input, which is what stimulates people to make an evaluative judgment, the positive motivational system responds more than the negative motivational system (positivity offset). As evaluative input increases, however, the negative motivational system usually responds more intensely (negativity bias). Since the available evaluative input related to clinical trial enrollment was rather limited, given the amount of information presented in a survey questionnaire, it is possible that a positivity offset was at work to shape our respondents' responses, resulting in the stronger impact of optimistic feelings on key dependent variables. Further, Ito and Cacioppo (2005) found that individual variability exists in these affective asymmetries related to evaluation. Individuals with a stronger positivity offset tend to respond with even more positivity in relatively neutral situations than individuals with a weaker positivity offset. Comparing the two samples, a much higher proportion of the LLS respondents have participated in clinical trials, and they also reported more positive attitudes toward clinical trials in general. Therefore, it was not surprising that positive emotions had a stronger impact overall on other evaluative responses to the survey questions, especially among the LLS respondents.

As for normative beliefs, even though its influence on information seeking and processing were rather similar across the two samples (see Chapters 3 and 6), it seemed to have stronger relationship with behavioral intentions in the national sample. The consistent direct relationships between informational subjective norm and information seeking and processing supported the proposition of a more direct linkage between these components of the RISP model. Reviewing the practical implications drawn in previous chapters, even though creating pro-enrollment social norms could

be an effective strategy for communication campaigns, it also brings about important ethical concerns. As Beauchamp and Childress (1994) mentioned, in relation to participation in biomedical research, “the primary function and justification of informed consent is to enable and protect individual autonomous choice” (p. 142). If we believe that the decision to enroll in a clinical trial should come from nothing less than an autonomous authorization from the individual, does the emphasis on social influence lead to an unethical manipulation of individuals’ free will? Based on results from Chapter 5 and Chapter 6, normative beliefs’ relatively weaker influence on cancer patients’ and their caregivers’ intentions to enroll in a future trial seem to offer a solution for ethical health communication practice. That is, even though normative beliefs were effective in motivating both routine and non-routine information seeking and greater systematic processing among prospective healthy volunteers, cancer patients and their caregivers were less likely to base their enrollment decisions on these beliefs. Therefore, if a campaign message mainly stresses improving knowledge about clinical trial research as a socially desirable behavior, instead of framing clinical trial participation as the ideal option for all patients, it could still facilitate informed decision making without compromising individual autonomy. However, similar to the challenge of maintaining hope without inducing unrealistic optimism among cancer patients, as underscored in earlier chapters, using social norms to improve the communications of clinical trial enrollment will be another delicate balancing act for health communicators.

Treated as a proxy measure for relevant channel beliefs, individuals’ general trust in their physicians had limited impact on systematic processing in the national sample and on positive attitudes in the LLS sample. Among other variables included in these analyses, awareness was significantly related to non-routine information seeking in both samples and on cancer patients’ behavioral intentions; prior experience

was also significantly related to cancer patients' positive attitudes. However, since these relationships did not remain consistent throughout different chapters, no further elaboration seems necessary here. Nonetheless, these findings, along with other RISP propositions that did not receive empirical support in this dissertation deserve future attention by communication researchers.

Future Research

A tentative adjustment of the RISP model, based on this dissertation and other studies reviewed in Chapter 2, is presented in Figure 7.1. The most important difference between the original RISP model and this newer version is the reconceptualization of information insufficiency. Specifically, the original RISP model argues that individuals' cognitive need to decrease the gap between current knowledge and the sufficiency threshold serves as the most fundamental motive for higher-level information seeking and processing. In the adjusted RISP model, this dynamic process is subjected to the type of uncertainties involved in the risk issue that is under investigation. In particular, when the risk issue entails a predictable outcome or a satiable uncertainty that could be minimized by information acquisition, information insufficiency will motivate information seeking and processing. When the risk issue is characterized by unclear outcome expectancy or an uncertainty that is unlikely to be resolved by more information, an alternative motive, such as an action tendency induced by affective responses, might be more likely to promote information seeking and processing activities. Motives related to the intention to defend or maintain one's social image, as related to normative beliefs, might also engender information seeking and processing activities.

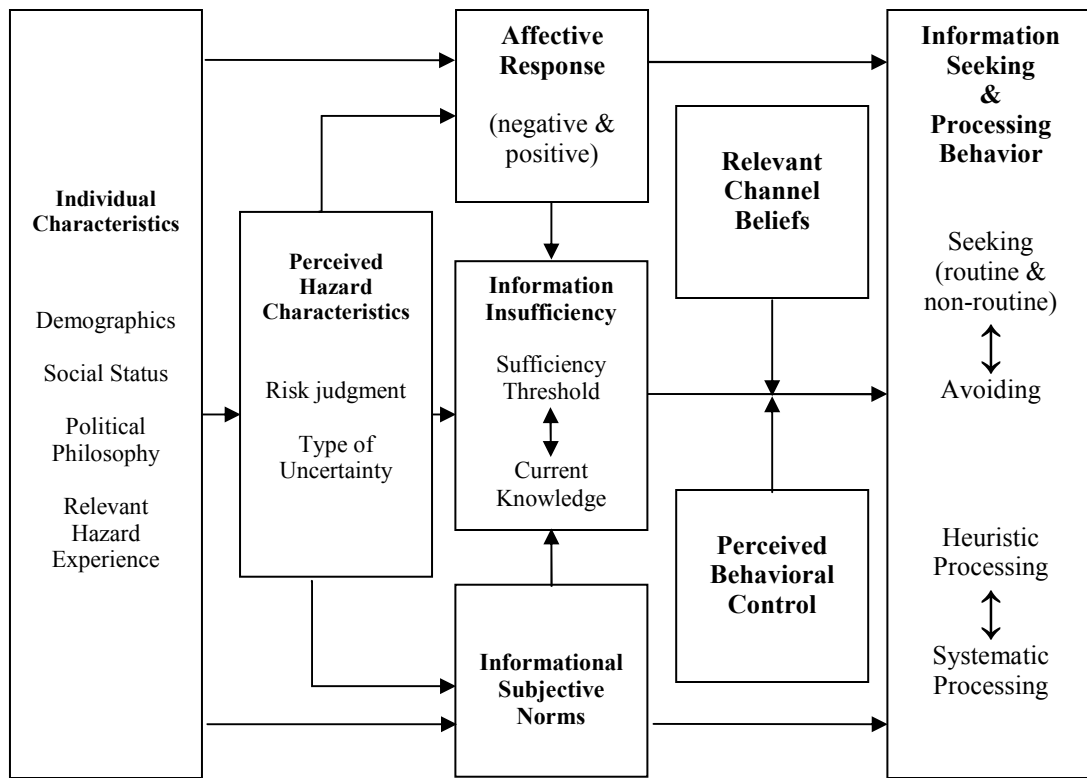


Figure 7.1
Adjusted RISP Model (adapted from Griffin et al., 1999)

Within the information insufficiency component, this reconceptualization depicts information sufficiency as a threshold that presents two additional possibilities, besides simply serving as an achievable cognitive state. That is, when one's perceived current knowledge exceeds their information sufficiency threshold, the lack of information insufficiency might deter individuals from engaging in communication activities because the task of information seeking and processing might not seem relevant or important enough. Alternatively, if the goal of reaching information sufficiency is too daunting, the gap between current knowledge and a sufficiency threshold also might not lead to greater seeking and processing because these tasks would be beyond one's capacity. That is, the sense of information insufficiency might

lead to varying degrees of information seeking and processing depending on whether it is feasible, or possible, to achieve information sufficiency. In addition, this adjusted RISP model also includes direct paths from affective responses and normative beliefs to information seeking and processing, as well as linkages between perceived hazard characteristics to information insufficiency. Within this framework, however, future research should continue to test and refine the RISP model. Informed by findings from this dissertation, here are some next-steps that I would like to take.

Compared to past analyses based on the RISP model, information insufficiency did not function well as the most fundamental mechanism that accounts for individuals' motivations for active information seeking and higher level information processing. Several factors might have contributed to this unexpected result. First, based on descriptive statistics, earlier studies have reported mean scores for current knowledge in the range of mid-30s, whereas the mean score for information sufficiency threshold was mostly around mid-60s. In contrast, data gathered in this project have presented some oddity. The mean score for current knowledge in the national sample ($M = 26.27$, $SD = 28.95$) was much lower than that from the LLS sample ($M = 50.68$, $SD = 30.92$), while responses to information sufficiency threshold fared similarly in the national sample ($M = 85.35$, $SD = 21.89$) and in the LLS sample ($M = 84.28$, $SD = 18.59$). In addition, a large proportion of the respondents in the national sample marked zero for current knowledge and 100 for information sufficiency threshold. Even responses from the LLS sample have mainly concentrated at 100 for information sufficiency threshold. Therefore, data distributions were heavily skewed for these two variables. Remedies such as data transformation were performed before these variables were used in inferential statistical analyses, but they failed to generate significant results after all.

From a conceptual front end, information insufficiency might have failed to

fulfill its role as the key motive for information seeking and processing due to the RISP model's lack of a mechanism that allows for adequate contextualization across different research settings. As Griffin et al. (2008) mentioned, the RISP model is a work in progress, which is to say that as compared to a formalized theory, it is a theoretical framework that is falsifiable and adjustable. This dissertation has adopted the measurement strategy that all previous published studies of the RISP model have used. Data collection, which included careful design and pre-test of the questionnaire, professional sampling, and scrupulous conduct of the survey instrument, was a scrutinized process. All of these efforts should have ensured that measurement error would not have impacted the results to any greater extent than it would have in past studies. Thus, the proposed adjustment to the RISP model seems necessary to allow for greater applicability of the model to different research contexts. In particular, the current research context for this dissertation, which involves health decision making related to clinical trial enrollment, determines that the uncertainty embedded in the risk issue here involves more than "a lack of knowledge" (Mieg, 2001). In other words, risks and uncertainties involved in clinical trials might be better accounted for or addressed as an emotional issue or a relational concern.

In particular, MacKenzie (1998) argues that one's viewpoint influences the amount of uncertainty that he or she perceives. Users, for example, of a given technology, tend to perceive the least amount of uncertainty, whereas developers of an alternative technology that addresses similar problems tend to perceive the highest degree of uncertainty. The developers or proponents of the original technology usually fall in the middle of what MacKenzie calls the "uncertainty trough." Applying this argument to the current problem, it is likely that respondents from the national sample and the LLS sample might position themselves at different parts of this trough. LLS respondents, especially cancer patients, are either already or likely future participants

of clinical trials. As compared to prospective healthy volunteers, they may have less uncertainty and, therefore, might not view the cognitive need for information sufficiency as the most urgent reason to engage in communication activities related to clinical trials.

On a related note, as a self-selected group of LLS members, their shared identity as cancer patients or caregivers might also have driven them to certain response patterns to the questionnaire. For instance, the desire to maintain hope, the proclaimed high trust in physicians, and the expression of positive attitudes toward clinical research might all have been rather unique to this particular group. Based on this speculation, another possible pathway for theory development is to specify a clearer scope condition for the RISP model. In particular, when it is reasonable to assume a common identity for the targeted audience, the RISP model might not function as well to depict within-audience variation in risk-related information seeking and processing. This conjecture may ignite future empirical exploration.

Nonetheless, comparing to past studies based on the RISP model, which have examined communication issues related to fish consumption, drinking water quality, global warming, urban flooding, and renewable energy, for a distant topic like clinical trial enrollment, using raw score estimates to assess current knowledge and information sufficiency might not have been the most ideal measurement strategy, especially in the national sample. Raw score estimates have traditionally been used to assess information insufficiency because research into meta-cognition has indicated that individuals can “evaluate and monitor their own cognitive processes and memory” (Griffin, Neuwirth et al., 2004, p. 36). However, when collecting data through a telephone survey with specific time constraint for each question, this strategy might not have allowed respondents to fully contemplate on what they already know and how much more they would need to know about a particular issue. Future research,

depending on the method for data collection, might need to consider alternative strategies to measure this construct.

Based on the sufficiency principle, information insufficiency primarily deals with a mental calculation related to judgment confidence. Related to motivations for communication behaviors, it describes the sense of uncertainty that individuals experience before engaging in information seeking and processing. Looking beyond survey instrument, therefore, a controlled experiment might offer a more precise assessment for this concept. For instance, one possible design is to develop a type of knowledge-based test or “quiz” that manipulates how much subjects believe they know about clinical trials and then tests the impact of this manipulation on their subsequent information seeking and processing. Specifically, research subjects could be randomly assigned to one of three conditions: confidence reducing, confidence boosting and the control group. After taking the knowledge test, researchers will inform them of an arbitrary score, perhaps even offering a comparison to an average score of some sort. This evaluation is expected to either reduce or boost their confidence in their current knowledge level. They will then have an option to end their participation without requesting more information about clinical trials or taking a tutorial about this topic on a computer. Besides time spent on getting more information, the number of pre-embedded links that they click could also be tracked to measure their engagement in information seeking and processing. Following the key assumption of the RISP model, participants in the “confidence reducing” condition are expected to score higher on the dependent measures than those in the “confidence boosting” condition.

Besides a more stringent measure for information insufficiency, another important task to further improve the RISP model involves the relevant channel belief component, which has always been the weakest predictor in the model. Given the

current research context, Chapter 4 and Chapter 5 tested using trust in doctors as a proxy measure for individuals' beliefs about the most important information channel where they could obtain information about clinical trial enrollment. In contrast, informed by Kahlor's augmented risk information seeking model, Chapter 3 included general attitudes toward clinical trial participation to assess its influence on routine and non-routine information seeking. Both strategies have limitations given their assumptions about where information about clinical trial enrollment is generally located. Using attitudes toward clinical trial participation, rather than attitudes toward information seeking activities, was even further removed from the conceptual meaning of this component. Reflecting on the cost-benefit analysis approach adopted in past research, further investigation is necessary to determine whether it is sufficient to measure individuals' beliefs about the usefulness and accessibility of the information from specific channels, or if relational aspect such as trustworthiness is indeed worthy of consideration. As Case (2002) argued, information seeking is a fundamental human behavior that should not be constrained or even linked to specific sources or channels. However, if we wish to assess how specific sources or channels in turn influence information seeking, or how beliefs associated with these sources and channels influence information seeking, it will be meaningful to search for an appropriate pathway without limiting our research scope too much.

Similar to relevant channel beliefs, perceived information gathering capacity is another RISP component that deserves more attention in the next stage of my research. Given the limited space in the questionnaires, this construct did not get an adequate assessment in this dissertation. However, as an important part of the RISP model, it was developed based on the idea of capacity from dual-processing theories, as well as the notion of self-efficacy from the TPB. Thus, a clearer conceptualization and assessment for this construct are necessary in future studies. In this dissertation, this

component was included as part of the analysis in Chapter 5, but it failed to show any significant impact on cancer patients' attitudes and behavioral intentions related to clinical trial enrollment. Since the capacity required for communication behaviors related to clinical trial enrollment could be complex and difficult to measure, this concept was purposefully left out from most other parts of this dissertation. Future research, however, needs to investigate not only its direct impact on health-related information seeking and processing, but also test possible interactions between gathering capacity and relevant channel beliefs in moderating the effect of information (in)sufficiency. As Griffin et al. (2005) pointed out, when an individual weighs the likelihood that a channel could deliver useful information versus the amount of effort he or she would need to invest, channel beliefs and capacity are very likely to work together to determine subsequent communication behaviors.

Tracing back to the main purpose of the current dissertation, which is to facilitate informed health decision making through the improvement of communications, another important issue with broader societal impact is to identify the boundary for informed decision making related to clinical trial enrollment. That is to say, when we focus on encouraging individuals to make informed, uncoerced choices to participate in a clinical trial, are we appealing to personal responsibility to an excessive degree or even forcing the decisions onto individual patients? For those who feel perfectly comfortable to rely on their physicians to make a decision for them, what would qualify a third party to decide whether the decision would work to their benefit? In other words, are informed, autonomous health decisions always the best decisions? The present dissertation does not offer answers to this paradox, as it was operationalized under the assumption that an ethical conduct for clinical trial enrollment has to be based on the free will of the participant. Nonetheless, future research should address these issues. As Guttman and Ressler (2001) pointed out,

communication campaigns that promote personal responsibility should recognize the conflicting demands they elicit. When we emphasize the importance of independent decision making, we should also acknowledge that expertise and experience are essential to good decisions sometimes, especially for health-related decisions. Thus, it is not feasible to anticipate that all the patients will make the decision for clinical trial enrollment on their own, no matter how equipped with information they are or how willing they are to do so.

To continue this research effort, future studies should also address several limitations reflected in this dissertation. For instance, additional measures are necessary for those RISP components assessed with a single item, such as positive affective responses and informational subjective norms. Besides risk judgment, other dimensions of the perceived hazard characteristics component, such as causal attributions and institutional trust, might suit other research contexts more to represent this construct. The routine and non-routine information seeking activities examined in Chapter 3 were subjected to an arbitrary categorization. In our current media environment, it is perhaps debatable that newspaper, radio, and television are more probable environment for casual information exposure as compared to online sources. This is especially true for health-related information that is widely available through health organizations and online patient advocacy groups. In fact, typing in “clinical trial” in Google search generates about 9,990,000 results. Thus, in addition to studying individuals’ motivation for information seeking, it is conceivably a more critical issue to investigate how to promote greater systematic processing of health and risk information that is readily available. On a related note, given the varying degrees of impact from cognitive processing, affective responses and social norms on attitude formation and behavioral intention across the two samples, even though no comprehensive framework that links the RISP model and the TPB is presented in this

dissertation, these associations await more formal theory building in the future.

Conclusion

To facilitate informed decision making related to clinical trial enrollment, this dissertation adopts a risk communication theoretical framework, the Risk Information Seeking and Processing model, to identify socio-psychological factors that motivate communication behaviors such as information seeking and processing. In comparing the responses from a national sample of primarily healthy respondents and a sample of cancer patients and their caregivers, interesting psychological mechanisms related to risk perception, affective responses, trust, and normative beliefs emerged as the main driving force behind these communication behaviors and subsequent attitude formation and behavioral intentions related to clinical trial enrollment. Even though hundreds of studies have sought to understand the low patient accrual rates for clinical trial research in the United States, few have guided their investigation with established communication theories. This dissertation attempts to introduce the RISP model to this context of health decision making, which also represents my conviction that various disciplines of communication research should inform and advance each other.

Along with the theoretical pursuit to test and refine the RISP model, this dissertation also generates important practical and ethical implications to improve the communications of clinical trial enrollment. To be most effective, the dissemination of information related to clinical trial research needs to go along with mechanisms that monitor current and prospective participants' emotional reactions to the conduct of patient accrual. Working to create a social environment that recognizes the value of clinical trial studies in advancing scientific knowledge will also benefit medical researchers and ordinary citizens in the long run.

APPENDICES

Appendix 1. IRB Approval Application (approved on June 12, 2007)

INITIAL APPROVAL REQUEST for Social and Behavioral Studies Involving Human Participants

For IRB Use Only
IRB ID# 07-06-025

CORNELL UNIVERSITY
Institutional Review Board

Click in shaded fields to enter information

SECTION I

Name of Investigator: Dr. Katherine A. McComas
Email address: kam19@cornell.edu
Campus address: 313 Kennedy Hall
School & Department: CALS & Communication
Administrative Mgr.: Ann Bianchi
Status: ☒ Faculty ☐ Ph.D. candidate
☐ Post-doc ☐ Staff

Title of Project: Improving methods for patient accrual to clinical trials

Other Members of Research
Teams (include students):

Zheng Yang (PhD student) Communication, Cornell
Ithaca

Have all investigators and other researchers working on this project successfully passed the IRB, the NIH, or another university's human participant's training online? ☒ Yes ☐ No
If not, you need to inform them that Cornell must have written documentation of training in human participant protection.

Start Date of Project (initial contact with subjects): August 1, 2007 Estimated End Date of Project: July 31, 2008

1. Is this research funded by an external (non-Cornell) sponsor(s)? ☒ Yes ☐ No ☐ Pending approval

If Yes (or Pending), what is the name of the sponsor(s)? Leukemia and Lymphoma Society

If you know the project's SPS #(s), please provide: _____

If you are awaiting funding to develop instruments and/or consent forms, etc., please check here: ☒ (Draft instruments are included with this application. Final instruments will be submitted before initiation of contact with potential participants.)

If this is a new proposal, please submit a copy of the proposal.

2. Is this research being conducted for a course? ☐ Yes ☒ No

If Yes, name of course: _____

Name of instructor: _____

3. Is this research being conducted for your thesis or dissertation? ☐ Yes ☒ No

If Yes, attach a copy of your thesis or dissertation proposal.

4. REQUIRED: Provide in layman's terms a brief summary description of the hypotheses or goals (if applicable). Limit to one paragraph.

Low patient accrual in clinical trials poses a serious concern for the advancement of medical science in the United States. This research will apply the model of Risk Information Seeking and Processing (RISP) and the Theory of Planned Behavior to examine factors that influence people's communication behaviors related to information seeking and processing about clinical trials and subsequent behavioral intentions. We aim for this study to lay the groundwork for a multi-year research program that seeks to investigate pathways to decision making about clinical trial enrollment. The overall aim of the project is to investigate factors underlying low enrollment in clinical trials in an effort to provide data-supported recommendations for the accrual of patients in clinical trials.

5. Describe the design of your research and planned use of human participants. Be sure to include the specific location at which any interaction with human participants will take place. (Please limit to a maximum of one page.)

We will conduct a random telephone survey of samples (500 adults per sample) from two populations: (a) the Leukemia and Lymphoma Society (LLS) and (b) the U.S. Having the two samples will allow us to compare the communication behaviors of LLS members to the general population. To collect the data, we will contract with Cornell's Survey Research Institute (SRI). All contact will occur via telephone, with the interviewer being at SRI and the respondent being contacted and interviewed at their home number. Interviews will average 25 minutes.

6. Will you ship any biological or diagnostic samples/specimens as part of this research?
☐ Yes ☒ No

If Yes, please contact the Biological Safety Officer at Environmental Health & Safety (4-4888 or fac2@cornell.edu) for specific shipping requirements.

7. Outline possible benefits the proposed study may provide to an individual participant, social group, or society. If there are no direct benefits to the participants as individuals, please state this explicitly here.

There are no direct benefits to the participants as individuals. The benefits to this study will occur primarily at the societal level through the development of an enhanced understanding of the factors that underlie individual intentions to seek information about clinical trials. We hope that this data will form the first step in developing evidence-based recommendations for enhanced (and ethical) patient accrual in clinical trials.

8. Please outline possible risks to participants in your study, including special or select types of participants.

We believe there are no risks to participants beyond what would be expected in everyday life.

9. Please describe the steps you have taken to minimize risk to participants.
Standard methods to protect privacy will be maintained. The identities of participants will not be associated with their responses. Data will be securely stored in the Principal Investigator's office on the Principal Investigator's computers, several hard disks, and audiotapes. Hard copies of data will remain in the possession of the researchers in the Principal Investigator's office. All data will be destroyed (i.e., shredded or erased) when their use is no longer needed but not before a minimum of five years after data collection.

10. Does this study involve secondary data analysis or restricted/limited data (includes HIPAA)? ☐ Yes ☒ No

If Yes, provide a brief description in the field below of each dataset and *indicate from which databank(s) or source(s) the data will be (has been) obtained*. For each dataset, please include the following information:

- a. Can the names or identities of participants in the dataset be deduced from the data fields?
- b. Is the dataset public-use (no restrictions on use) OR is the dataset restricted or limited access?
If restricted or limited access, attach a copy of the licensing agreement you signed with the distributor, as well as a copy of your data security plan.
- c. Are you planning to merge geographic, company, census, community or other potentially identifying data into an individual-level dataset during the course of this project? ☐ Yes ☐ No
If yes, attach a description of how you plan to protect the data from unauthorized use.
- d. Will anyone other than you have access to any restricted or limited access dataset(s)?
☐ Yes ☐ No
If yes, provide their names, and ensure that they have completed the required education in the use of human participants. Submit copies of affidavits, non-disclosure agreements, or similar documents they were required to sign with the distributor.

*If your study involves secondary data analyses only, please skip to Section II, question 18.
For all other studies, please fill out the remaining questions.*

SECTION II

Please answer the remaining questions thoroughly and completely.

1. How many participants do you plan to recruit for the entire study? 1,000
2. What is the expected age range of participants? 18 to 99 years [Note: this must match all attached documents submitted.]
3. Will your participant sample include Cornell University students? ☐ Yes ☒ No
If Yes, answer a. – c. below:
 - a. do you plan to recruit participants from classes that you personally teach? ☐ Yes ☐ No

If Yes, provide a justification for the collection of data from your own students in #8 below.

b. will participants be obtained from the Psychology Dept. SUSAN website? ☐ Yes
☐ No

c. will participants be obtained from the University Registrar? ☐ Yes ☐ No

4. Please estimate: Proportion of female participants 50% Proportion of minority participants (U.S. only) 20%

5. Explain how you plan to recruit your participants. Specify the exact wording of requests, notices, or advertisements recruiting subjects. Attach draft advertisements, flyers, letters, or descriptions posted on SUSAN. (Please also indicate the specific locations where participants will be recruited.)

National sample: We will use random digit dialing to complete telephone interviews with 500 adults residing within the United States. The sample selection procedures will ensure that every telephone household within the United States has an equal chance to be included in the survey, and that once the household is sampled, every adult will have an equal chance to be included in the poll. We are still preparing the exact wording of requests to participate but will send a copy to IRB prior to any contact with potential participants.

LLS sample: The LLS will provide us with a list of members and their telephone numbers who have consented to be contacted for the survey. From this list, we will use random selection of names to complete interviews with 500 adult members. Even though members may have consented to be contacted, we will assure them that they still have the right to decline to participate in the interview. Members of the LLS will include both individuals with cancer, as well as individuals without cancer (e.g., caregivers, family members, health care workers). We do not plan to target more (i.e., oversample) from one group or another at this time. If this changes, we will notify the IRB prior to any change in recruitment. Finally, as with the national sample, we are still preparing the exact wording of requests to participate but will send a copy to IRB prior to any contact with potential participants.

6. Will participants be compensated for their time? ☐ Yes ☒ No
If Yes, please describe the compensation.

7. Do you plan to use email or the Internet to recruit your participants? ☐ Yes ☒ No
If Yes, you should be aware that email and Internet transmission are neither private nor secure. Please include a sentence in your consent document that alerts participants that there is a chance their answers could be read by a third party.

8. Check which category(ies) of participants will be included in your study. For all categories other than the first (mentally competent adults), additional safeguards are required to protect these populations from undue influence/coercion in the recruitment process, risk during the study, etc. Explain the additional safeguards to be provided.

☒ Only mentally competent adults or secondary analyses of existing data

☐ Children under 18: Active, written parental consent is a federal requirement, unless

waived by IRB after review. It is generally expected that you also obtain the *written assent* of minors 7 years of age and older. Attach copies of parental consent form (and minor's assent form when applicable).

- ☐ Employees of the investigating group: Please justify the use of this group, and explain how undue coercion in the recruitment process will be avoided.

- ☐ Students enrolled in your own classes: Please justify the use of this group. Federal regulations discourage the use of students enrolled in classes taught by principal investigators.

- ☐ Cognitively-impaired persons: How will you screen potentially cognitively-impaired subjects to determine when proxy consent is required? Attach copy of proxy consent form, and subject assent form (if appropriate).

- ☐ Pregnant or nursing women

- ☐ Prisoners or juveniles under detention or on probation

- ☐ People in foreign countries: Please describe how you are collaborating with the local communities, government, or other institutions (as relevant to your project), and include documentation as appropriate.

- ☐ Other potentially vulnerable participants: Who, and why?

9. Check additional sources of data that will be used in your study.

- ☐ None
☒ Census/public records
☐ Discarded human materials
☐ Medical records
☐ Registries (e.g. cancer registry) Name of registry: _____
☐ Blood, urine, or tissue samples
☐ Other (explain) _____

10. Duration of participant's participation, through each component of the study, and in total. Please provide full information for each component of the study.

All telephone interviews will be conducted using a Computer Assisted Telephone Interviewing (CATI) software system, with the average interview length of around 25 minutes.

11. Check any/all of the following procedures that apply to your study. For *each* procedure

checked, 1) explain the procedure in detail, and 2) provide the ethical and scientific justification for employing the procedure.

- ☐ Deception (When and how will the participants be debriefed? Generally, the nature of the deception and its necessity should be explained to the participants. Attach a copy of your debriefing form/script.)

- _____
- ☐ Punishment: _____
- ☐ Use of drugs: _____
- ☐ Covert observation: _____
- ☐ Induction of mental and/or physical stress: _____
- ☐ Procedures that risk physical harm to the subject: _____
- ☐ Materials commonly regarded as socially unacceptable: _____
- ☐ Procedures that might be regarded as an invasion of privacy: _____

12. Is confidentiality promised to the participants? ☒ Yes ☐ No If No, please explain.

- _____
- a. If confidentiality is promised, will access to names be under your exclusive control?
☐ Yes ☒ No
If No, who else will have access to the names, and what will be done to protect the confidentiality of the subjects? Because we will contract with Cornell's Survey Research Institute (SRI) for data collection, people working at SRI will have access to the names while conducting interviews and entering data. The SRI will follow appropriate IRB procedures to ensure that the data are securely stored.
- b. Where will the names be recorded (e.g., on test protocols, on a separate list with code numbers, in a computer file, etc.)? Names of participants will be recorded in the aggregate data file sent to the Principal Investigator.
- c. For what purpose(s) will names be recorded? For record-keeping purposes only. Names will never be associated with responses.
- d. If confidentiality is promised, what additional steps are you taking to keep their data secure? Cornell's SRI is a professional research agency, and they will ensure the data are securely stored. The Principal Investigator and other member of the research team will have access to the names of the respondents in the aggregate data file, but names will never be associated with responses. In addition, all data will be de-identified prior to their being shared with anyone other than the PI or Zheng Yang.
- e. Will names of participants be included in any publication based on this study? ☐
Yes ☒ No
If Yes, for what reason(s)? _____

13. Will any data be gathered through photographic, video or sound-recording devices? ☐
Yes ☒ No

If yes, answer a.-d. below, and be sure to include all this information on your consent form(s) as well as provide a separate signature line for the participants to agree to be video/audio taped and/or photographed.

- a. What types of recording devices will be used and what will be recorded? _____

- b. Please provide scientific justification for gathering data using the device(s) enumerated above. _____
- c. What will be done with the still photos, video or audio recordings after the study has concluded? (I.e., used in publications, presentations, etc.) _____
- d. When, if ever, do you plan to destroy these records (specify when for each type)? _____
- e. How will you protect the confidentiality of the materials produced by such devices (if so promised)? (Remember that faces alone reveal identity, even if captions with names are not provided.) _____

14. Sometimes research findings are presented in a manner that permits knowledgeable readers to infer the identity of a person used as a participant, even if names are omitted. Do you expect to present findings that may possibly provide such clues? ☐ Yes ☒ No ☐ Confidentiality not promised

If Yes, explain how you will protect the identity of participant, or alternatively how you will explain to them that their confidentiality cannot be absolutely protected. This information should also be conveyed to participants on the study consent form.

15. Will information be obtained pertaining to persons other than immediate participants (e.g., their friends)? ☒ Yes ☐ No

If Yes, how will the confidentiality of such persons be protected? If their confidentiality is not promised, please explain here.

Information pertaining to persons other than immediate participants will be obtained with no identification to any particular individual. Only questions regarding general behavior tendencies or patterns will be asked. For example, respondents will be asked if they are aware of any people they know who have participated in clinical trials, but we will not ask respondents to identify those people by name.

16. Do you intend to obtain written consent? ☐ Yes ☒ No

If Yes, refer to *Required Components of Informed Consent Documents* on the IRB website attach a copy of the consent form. If collecting data from minors you must address both parental consent and the child's assent.

If No, please answer questions a – c below.

- a. Why do you not intend to use such forms? This must be a strong argument (i.e., scientific validity).

Oral consent will be requested at the beginning of telephone interviews. A respondent's actual participation in the interview will indicate that they fully understand the purpose of the research and consent to participate.

- b. In what manner and to what extent will you give potential participants advance information about the study procedures? If using a contact letter, please attach it.

Study procedures will be explained at the beginning of the telephone survey.

- c. In what manner will potential participants be advised that their participation and continuation in the project is entirely voluntary? Please provide a copy of the text to be used.

Potential participants will be advised that their participation and continuation in the project is entirely voluntary at the beginning of the telephone survey. They have every right to refuse to participate or to discontinue the interview at any time during the process.

17. If proposing to use oral consent (e.g., telephone survey, illiterate subjects), provide a copy (script) of the text that you will use.

This text is currently being prepared. I will send IRB a copy for approval prior to any contact with potential participants.

18. Has this study been reviewed (or will it be reviewed) by another institution's Institutional Review Board (IRB) or another ethical review body (including Cornell Medical)?

☐ Yes ☒ No

If already reviewed, attach a copy of the approval/deferral notification you received from that IRB. If this study will be submitted to another IRB, please indicate below the institution and give the approximate date for the review.

Financial Conflict of Interest Disclosure (non-student investigators only)

In order to fulfill the requirements of federal regulations, investigators conducting research involving human participants at Cornell must disclose known *significant financial interests* that would reasonably appear to be affected by the research project. Significant financial interests include:

- An equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children exceeds \$10,000 in value, or represents more than 5% ownership interest in a single entity
- Salary, royalties, or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children over the next twelve months are expected to exceed \$10,000

1. Have you and all key *faculty* personnel on this project completed the Annual Disclosure Statement? ☒ Yes ☐ No
2. Have you and all key personnel disclosed all significant financial interests (including those of spouses and dependent children) that would reasonably appear to be affected by this research project? ☒ Yes ☐ No
3. Do any of the investigators, their spouses or dependent children, have any significant financial interests that would reasonably appear to be affected by this research? ☐ Yes ☒ No
4. Do any of the investigators, their spouses or dependent children, have any financial interest or other relationship with any company or entity that sponsors or supports this research? ☐ Yes ☒ No

If you answered Yes to either #3 or #4, the Chair of IRB must receive a letter from your dean or director stating in summary form how any potential financial conflict of interest

involving this research project has been reduced, managed or eliminated. *The IRB is not able to review this project until receipt of the dean's/director's letter.* Please address the letter to: IRB Chair, 35 Thornwood Drive, Suite 500.

Approximate date the IRB Chair can expect to receive the letter: _____

Appendix 2A. National Sample Questionnaire

Clinical trials are studies that use volunteer patients to test new drugs, treatments, or new uses for approved drugs and treatments.					
1. Have you ever heard about opportunities to enroll in clinical trials? <0> Never heard about opportunities <1> Only a little <2> Some <3> Quite a bit <4> A great deal					
2. To the best of your knowledge, have you ever enrolled in a clinical trial? If yes, how many times? If no, do you know anyone else who has? (SRI coding)					
3. If you were given an opportunity to enroll in a clinical trial, how likely is it that you would?	No chance at all	Not very likely	Somewhat likely	Very likely	Unsure
4. How likely is it that you would encourage someone you care about, such as a friend or family member, to enroll in a clinical trial?	No chance at all	Not very likely	Somewhat likely	Very likely	Unsure
5. Now, we would like you to rate how much you know about enrolling in clinical trials. Using a scale of zero to 100, where zero means that you know nothing and 100 means that you know all there is to know, how much do you think you know right now about enrolling in clinical trials?			Write-in Below 0-100 [998=DK/999=refused] <q1>		
6. Think of that same scale again. This time, we would like you to estimate how much you think you would need to know in order to fully understand how to enroll in clinical trials, with zero meaning that you would need to know nothing and 100 meaning that you would need to know all there is to know.			Write-in Below 0-100 [998=DK/999=refused] <q2>		
6A. => +1 if (q5+q6<=100) You rated your current knowledge about enrolling in clinical trials as <q5> and said you need to know <q6> to fully understand. Are you saying that you need to know <q6> more than you already do, or are you saying that <q6> is all you need to know?			Need to know <q6> more = 1 <q6> is all I need to know=2 [998=DK/999=refused]		
7. Now, we would like you to rate how informed your think your doctor is about clinical trial enrollment. Using a scale of zero to 100, where zero means that your doctor knows nothing and 100 means that your doctor knows all there is to know, how much do you think your doctor knows right now about enrolling patients in clinical trials?			Write-in Below 0-100 [998=DK/999=refused]		
8. Do you think that enrolling in a clinical trial could put your health at risk? Please use a scale from zero to 100, where zero means that it would have no risk whatsoever, and 100 means that it is certain to put your health at risk.			Write-in Below 0-100 [998=DK/999=refused]		
9. If it were to put your health at risk, how serious do you think the risk would be? Please use a scale of zero to 100, where zero means not serious at all and 100 means it would be as			Write-in Below 0-100 [998=DK/999=refused]		

serious as it could possibly be?					
10. Do you think that standard medical treatment for an illness could put your health at risk? Please use a scale from zero to 100, where zero means that it would have no risk whatsoever, and 100 means that it is certain to put your health at risk.	Write-in Below 0-100 [998=DK/999=refused]				
Next are some statements that people have made about how they personally deal with information about enrolling in clinical trials. Please tell me whether each of these statements could apply to you using the following scale: <u>strongly disagree (1)</u> , <u>disagree (2)</u> , <u>feel neutral (3)</u> , <u>agree (4)</u> , or <u>strongly agree (5)</u> :					
11. People who are important to me want me to stay on top of information about enrolling in a clinical trial.	1	2	3	4	5
12. I feel comfortable talking to my doctor about enrolling in a clinical trial.	1	2	3	4	5
13. I have no problem bringing up the subject of enrolling in a clinical trial with my doctor.	1	2	3	4	5
14. If I want to, I can express my wishes to my doctor about enrolling in a clinical trial.	1	2	3	4	5
15. When the topic of enrolling in a clinical trial comes up, I'm likely to tune it out.	1	2	3	4	5
16. When I come across information about enrolling in a clinical trial, I focus on only a few key points.	1	2	3	4	5
17. I'm likely to go out of my way to get more information about enrolling in a clinical trial	1	2	3	4	5
18. After I encounter information about enrolling in a clinical trial, I'm likely to stop and think about it.	1	2	3	4	5
19. For me to understand about enrolling in a clinical trial, the more viewpoints I get the better.	1	2	3	4	5
20. When I see or hear information about enrolling in a clinical trial, I don't spend much time thinking about it.	1	2	3	4	5
21. I read or listen to information about enrolling in a clinical trial even if I don't agree with what it says.	1	2	3	4	5
22. There is more information on enrolling in clinical trials than I personally need.	1	2	3	4	5
23. I feel quite capable of finding the information I need about enrolling in a clinical trial.	1	2	3	4	5

24. Much of the information about enrolling in a clinical trial is too technical for me to understand.	1	2	3	4	5
25. I trust my doctor to protect me from any harm that I might face from enrolling in a clinical trial.	1	2	3	4	5
26. My doctor keeps up to date on the most modern, current treatments available to protect my health.	1	2	3	4	5
27. My doctor does not let his or her personal beliefs bias how he or she makes decisions about my health.	1	2	3	4	5
28. If I wanted to enroll in a clinical trial, I would enroll, even if my doctor did not support my decision.	1	2	3	4	5
The next section includes statements that other people have made about what they think is important to consider when deciding whether to enroll in clinical trials. Thinking about your own situation, please tell me whether you <u>strongly disagree (1)</u> , <u>disagree (2)</u> , <u>feel neutral (3)</u> , <u>agree (4)</u> , or <u>strongly agree (5)</u> with these statements. "Enrolling in a clinical trial..."					
29. Would make me feel like I am helping other people.	1	2	3	4	5
30. Would help advance medical research.	1	2	3	4	5
31. Would help me get better medical treatment.	1	2	3	4	5
32. Would be personally expensive for me.	1	2	3	4	5
33. Would cause me inconvenience.	1	2	3	4	5
Next, consider whether you <u>strongly disagree (1)</u> , <u>disagree (2)</u> , <u>feel neutral (3)</u> , <u>agree (4)</u> , or <u>strongly agree (5)</u> with the following statements. "When I think about enrolling in a clinical trial, I believe that..."					
34. Doing something good for other people would be worth the effort.	1	2	3	4	5
35. Helping to advance medical research would be worth the effort.	1	2	3	4	5
36. My getting better medical treatment would be worth the effort.	1	2	3	4	5

37. It would be worth the personal expense.	1	2	3	4	5						
38. It would be worth the inconvenience.	1	2	3	4	5						
39. The possible risks to my health beyond standard medical care would be worth the effort.	1	2	3	4	5						
40. I would care a lot about what my doctor thinks I should do.	1	2	3	4	5						
41. I would care a lot about what my friends, family members, and people who are important to me think I should do.	1	2	3	4	5						
Now we would like to know a little bit more about your feelings toward enrolling in clinical trials. Please use a number from 0 to 10, where 0 means you have “none of this feeling” and 10 means you have “a lot of this feeling.” When you think about enrolling in a clinical trial, how <u>[read adjective below]</u> do you feel ...											
42. Optimistic	0										10
43. Afraid	0										10
44. Worried	0										10
45. Anxious	0										10
On a scale of 0 to 10, where 0 is “none” and 10 is “a lot”, how much attention would you pay to information about enrolling in clinical trials from ...											
46. Family members	0										10
47. Friends and co-workers	0										10
48. Physicians and medical experts	0										10
49. Patient advocacy organizations	0										10

50. Pharmaceutical companies	0										10
51. Local newspapers	0										10
52. Local radio or television stations	0										10
53. Health magazines and newsletters	0										10
54. Health-related websites	0										10
55. Internet support groups	0										10
Now just a few more questions related to health:											
56. Have you ever been diagnosed with a chronic or acute illness? No (0) Yes (1) If Yes, are you: Currently in treatment (1) Diagnosed but not in treatment (2) The illness is currently under control or in remission (3) 998=DK/999=refused											
57. In the last 12 months, how many days have you seen a doctor or visited a medical clinic for any reason, including check-ups or visits to the emergency room or hospital outpatient department? (Range from 0 to 365 days)											
58. What year were you born?											
59. What is the last grade that you completed in school? (SRI Coding)											
60. What best describes your race? (SRI Coding)											
61. Household income (SRI Coding)											
62. Gender (Do not read out loud)											

Appendix 2B. LLS Sample Questionnaire

Clinical trials are studies that use volunteer patients to test new drugs, treatments, or new uses for approved drugs and treatments.					
1. Have you ever heard about opportunities to enroll in clinical trials? <0> Never heard about opportunities <1> Only a little <2> Some <3> Quite a bit <4> A great deal					
2. To the best of your knowledge, have you ever enrolled in a clinical trial? If yes, how many times? If no, do you know anyone else who has? (SRI coding)					
3. If you were given an opportunity to enroll in a clinical trial, how likely is it that you would?	No chance at all	Not very likely	Somewhat likely	Very likely	Unsure
4. How likely is it that you would encourage someone you care about, such as a friend or family member, to enroll in a clinical trial?	No chance at all	Not very likely	Somewhat likely	Very likely	Unsure
5. Now, we would like you to rate how much you know about enrolling in clinical trials. Using a scale of zero to 100, where zero means that you know nothing and 100 means that you know all there is to know, how much do you think you know right now about enrolling in clinical trials?			Write-in Below 0-100 [998=DK/999=refused] <q1>		
6. Think of that same scale again. This time, we would like you to estimate how much you think you would need to know in order to fully understand how to enroll in clinical trials, with zero meaning that you would need to know nothing and 100 meaning that you would need to know all there is to know.			Write-in Below 0-100 [998=DK/999=refused] <q2>		
6A. => +1 if (q5+q6<=100) You rated your current knowledge about enrolling in clinical trials as <q5> and said you need to know <q6> to fully understand. Are you saying that you need to know <q6> more than you already do, or are you saying that <q6> is all you need to know?			Need to know <q6> more = 1 <q6> is all I need to know=2 [998=DK/999=refused]		
7. Now, we would like you to rate how informed your think your doctor is about clinical trial enrollment. Using a scale of zero to 100, where zero means that your doctor knows nothing and 100 means that your doctor knows all there is to know, how much do you think your doctor knows right now about enrolling patients in clinical trials?			Write-in Below 0-100 [998=DK/999=refused]		
8. Do you think that enrolling in a clinical trial could put your health at risk? Please use a scale from zero to 100, where zero means that it would have no risk whatsoever, and 100 means that it is certain to put your health at risk.			Write-in Below 0-100 [998=DK/999=refused]		
9. If it were to put your health at risk, how serious do you think the risk would be? Please use a scale of zero to 100, where zero means not serious at all and 100 means it would be as serious as it could possibly be?			Write-in Below 0-100 [998=DK/999=refused]		

10. Do you think that standard medical treatment for an illness could put your health at risk? Please use a scale from zero to 100, where zero means that it would have no risk whatsoever, and 100 means that it is certain to put your health at risk.	Write-in Below 0-100 [998=DK/999=refused]				
Next are some statements that people have made about how they personally deal with information about enrolling in clinical trials. Please tell me whether each of these statements could apply to you using the following scale: <u>strongly disagree</u> (1), <u>disagree</u> (2), <u>feel neutral</u> (3), <u>agree</u> (4), or <u>strongly agree</u> (5):					
11. People who are important to me want me to stay on top of information about enrolling in a clinical trial.	1	2	3	4	5
12. I feel comfortable talking to my doctor about enrolling in a clinical trial.	1	2	3	4	5
13. I have no problem bringing up the subject of enrolling in a clinical trial with my doctor.	1	2	3	4	5
14. If I want to, I can express my wishes to my doctor about enrolling in a clinical trial.	1	2	3	4	5
15. When the topic of enrolling in a clinical trial comes up, I'm likely to tune it out.	1	2	3	4	5
16. When I come across information about enrolling in a clinical trial, I focus on only a few key points.	1	2	3	4	5
17. I'm likely to go out of my way to get more information about enrolling in a clinical trial	1	2	3	4	5
18. After I encounter information about enrolling in a clinical trial, I'm likely to stop and think about it.	1	2	3	4	5
19. For me to understand about enrolling in a clinical trial, the more viewpoints I get the better.	1	2	3	4	5
20. When I see or hear information about enrolling in a clinical trial, I don't spend much time thinking about it.	1	2	3	4	5
21. I read or listen to information about enrolling in a clinical trial even if I don't agree with what it says.	1	2	3	4	5
22. There is more information on enrolling in clinical trials than I personally need.	1	2	3	4	5
23. I feel quite capable of finding the information I need about enrolling in a clinical trial.	1	2	3	4	5

24. Much of the information about enrolling in a clinical trial is too technical for me to understand.	1	2	3	4	5
25. I trust my doctor to protect me from any harm that I might face from enrolling in a clinical trial.	1	2	3	4	5
26. My doctor keeps up to date on the most modern, current treatments available to protect my health.	1	2	3	4	5
27. My doctor does not let his or her personal beliefs bias how he or she makes decisions about my health.	1	2	3	4	5
28. If I wanted to enroll in a clinical trial, I would enroll, even if my doctor did not support my decision.	1	2	3	4	5
The next section includes statements that other people have made about what they think is important to consider when deciding whether to enroll in clinical trials. Thinking about your own situation, please tell me whether you <u>strongly disagree (1)</u> , <u>disagree (2)</u> , <u>feel neutral (3)</u> , <u>agree (4)</u> , or <u>strongly agree (5)</u> with these statements. "Enrolling in a clinical trial..."					
29. Would make me feel like I am helping other people.	1	2	3	4	5
30. Would help advance medical research.	1	2	3	4	5
31. Would help me get better medical treatment.	1	2	3	4	5
32. Would be personally expensive for me.	1	2	3	4	5
33. Would cause me inconvenience.	1	2	3	4	5
Next, consider whether you <u>strongly disagree (1)</u> , <u>disagree (2)</u> , <u>feel neutral (3)</u> , <u>agree (4)</u> , or <u>strongly agree (5)</u> with the following statements. "When I think about enrolling in a clinical trial, I believe that..."					
34. Doing something good for other people would be worth the effort.	1	2	3	4	5
35. Helping to advance medical research would be worth the effort.	1	2	3	4	5
36. My getting better medical treatment would be worth the effort.	1	2	3	4	5

37. It would be worth the personal expense.	1	2	3	4	5						
38. It would be worth the inconvenience.	1	2	3	4	5						
39. The possible risks to my health beyond standard medical care would be worth the effort.	1	2	3	4	5						
40. I would care a lot about what my doctor thought I should do.	1	2	3	4	5						
41. I would care a lot about what my friends, family members, and people who are important to me thought I should do.	1	2	3	4	5						
Next, consider how you feel about someone you care about, such as a family member or friend. Using the same scale from above, please say whether you <u>strongly disagree (1)</u> , <u>disagree (2)</u> , <u>feel neutral (3)</u> , <u>agree (4)</u> , or <u>strongly agree (5)</u> with the following statements. "When it comes to someone you care about enrolling in clinical trials..."											
42. Doing something good for other people would be worth the effort for them.	1	2	3	4	5						
43. Helping to advance medical research would be worth the effort for them.	1	2	3	4	5						
44. Getting better medical treatment would be worth the effort for them.	1	2	3	4	5						
45. It would be worth the personal expense for them.	1	2	3	4	5						
46. It would be worth the inconvenience for them.	1	2	3	4	5						
47. The possible health risks beyond standard medical care would be worth the effort for them.	1	2	3	4	5						
Now we would like to know a little bit more about your feelings toward enrolling in clinical trials. Please use a number from 0 to 10, where 0 means you have "none of this feeling" and 10 means you have "a lot of this feeling." When you think about enrolling in a clinical trial, how <u>[read adjective below]</u> do you feel ...											
48. Optimistic	0										10
49. Afraid	0										10

50. Worried	0										10
51. Anxious	0										10
On a scale of 0 to 10, where 0 is “none” and 10 is “a lot”, how much attention would you pay to information about enrolling in clinical trials from ...											
52. Family members	0										10
53. Friends and co-workers	0										10
54. Physicians and medical experts	0										10
55. Patient advocacy organizations	0										10
56. Pharmaceutical companies	0										10
57. Local newspapers	0										10
58. Local radio or television stations	0										10
59. Health magazines and newsletters	0										10
60. Health-related websites	0										10
61. Internet support groups	0										10
Now just a few more questions related to health:											

<p>62. Have you yourself ever been diagnosed with a chronic or acute illness?</p> <p>No (0) Yes (1)</p> <p>If Yes, are you:</p> <p>Currently in treatment (1) Diagnosed but not in treatment (2) The illness is currently under control or in remission (3) 998=DK/999=refused</p>
<p>63. Has someone you care for ever been diagnosed with a chronic or acute illness?</p> <p>No (0) Yes (1)</p> <p>If Yes, is the person you care for:</p> <p>Currently in treatment (1) Diagnosed but not in treatment (2) The illness is currently under control or in remission (3) Deceased (4) 998=DK/999=refused</p>
<p>64. In the last 12 months, how many days have you seen a doctor or visited a medical clinic for any reason, including check-ups or visits to the emergency room or hospital outpatient department?</p> <p>(Range from 0 to 365 days)</p>
<p>65. What year were you born?</p>
<p>66. What is the last grade that you completed in school? (SRI Coding)</p>
<p>67. What best describes your race? (SRI Coding)</p>
<p>68. Household income (SRI Coding)</p>
<p>69. Gender (Do not read out loud)</p>

REFERENCES

- Abraham, N. S., Young, J. M., & Solomon, M. J. (2006). A systematic review of reasons for nonentry of eligible patients into surgical randomized controlled trials. *Surgery, 139*(4), 469-483.
- Afifi, W. A., & Weiner, J. L. (2004). Toward a Theory of Motivated Information Management. *Communication Theory, 14*(2), 167-190.
- Agrawal, M., Grady, C., Fairclough, D. L., Meropol, N. J., Maynard, K., & Emanuel, E. J. (2006). Patients' decision-making process regarding participation in phase I oncology research. *Journal of Clinical Oncology, 24*(27), 4479-4484.
- Ajzen, I. (1988). *Attitudes, personality, and behavior*. Milton Keynes, UK: Open University Press.
- Ajzen, I. (1991). The theory of planned behavior. *Organizational Behavior and Human Decision Processes, 50*, 179-211.
- Ajzen, I. (2004). The directive influence of attitudes on behavior. In A. S. R. Manstead, N. Frijda & A. Fischer (Eds.), *Feelings and emotions: the Amsterdam symposium*. New York: Cambridge University Press.
- Ajzen, I., & Albarracin, D. (2007). Predicting and changing behavior: A reasoned action approach. In I. Ajzen, D. Albarracin & R. Hornik (Eds.), *Prediction and change of health behavior: Applying the reasoned action approach*. Mahwah, NJ: Lawrence Erlbaum Associates.
- Albrecht, T. L., Blanchard, C., Ruckdeschel, J. C., Coover, M., & Strongbow, R. (1999). Strategic physician communication and oncology clinical trials. *Journal of Clinical Oncology, 17*(10), 3324-3332.
- Albrecht, T. L., Egely, S. E., Gleason, M. E. J., Harper, F. W. K., Foster, T. S., Peterson, A. M., et al. (2008). Influence of clinical communication on patients' decision making on participation in clinical trials. *Journal of Clinical Oncology, 26*(16), 2666-2673.

- Albrecht, T. L., Ruckdeschel, J. C., Riddle, D. L., Blanchard, C. G., Penner, L. A., Coovert, M. D., et al. (2003). Communication and consumer decision making about cancer clinical trials. *Patient Education and Counseling*, 50(1), 39-42.
- Almeida, L., Kashdan, T. B., Nunes, T., Coelho, R., Albino-Teixeira, A., & Soares-da-Silva, P. (2008). Why volunteers for phase I clinical trials? Influences of anxiety, social anxiety and depressive symptoms on self-selection and the reporting of adverse events. *European Journal of Clinical Pharmacology*, 64(6), 575-582.
- American Cancer Society. (2008). *Cancer Statistics*. Atlanta, GA.
- Angell, M., & Kassirer, J. P. (1994). Clinical research: What should the public believe. *New England Journal of Medicine*, 331, 189-190.
- Aspinwall, L. G. (1998). Rethinking the role of positive affect in self-regulations. *Motivation and Emotion*, 22(1), 1-32.
- Aspinwall, L. G., & Brunhart, S. M. (1996). Distinguishing optimism from denial: Optimistic beliefs predict attention to health threats. *Personality and Social Psychology Bulletin*, 22, 993-1003.
- Atkinson, N. L., Saperstein, S. L., Massett, H. A., & et al. (2008). Using the Internet to search for cancer clinical trials: a comparative audit of clinical trial search tools. *Contemporary Clinical Trials*, 29(4), 555-564.
- Avis, N. E., Smith, K. W., Link, C. L., Hortobagyi, G. N., & Rivera, E. (2006). Factors associated with participation in breast cancer treatment clinical trials. *Journal of Clinical Oncology*, 24(12), 1860-1867.
- Bandura, A. (1977). Self-efficacy: Toward a Unifying Theory of Behavioral Change. *Psychological Review*, 84(2), 191-215.
- Baquet, C. R., Commiskey, P., Mullins, C. D., & Mishra, S. I. (2006). Recruitment and participation in clinical trials: Socio-demographic, rural/urban, and health care access predictors. *Cancer Detection and Prevention*, 30(1), 24-33.
- Barrett, R. (2002). A nurse's primer on recruiting participants for clinical trials. *Oncology Nursing Forum*, 29(7), 1091-1098.

- Barry, M. J., Fowler, F. J., Jr., Mulley, A. G., Jr., Henderson, J. V., Jr., & Wennberg, J. E. (1995). Patient Reactions to a Program Designed to Facilitate Patient Participation in Treatment Decisions for Benign Prostatic Hyperplasia. *Medical Care*, 33(8), 771-782.
- Battaglia, T. A., Ash, A., Prout, M. N., & Freund, K. M. (2006). Cancer prevention trials and primary care physicians: Factors associated with recommending trial enrollment. *Cancer Detection and Prevention*, 30(1), 34-37.
- Beauchamp, T. L., & Childress, J. F. (1994). The meaning and justification of informed consent. In T. L. Beauchamp & J. F. Childress (Eds.), *Principles of Biomedical Ethics* (Fourth ed., pp. 142-153). New York: Oxford.
- Bevan, E. G., Chee, L. C., McGhee, S. M., & McInnes, G. T. (1993). Patients attitudes to participation in clinical trials. *British Journal of Clinical Pharmacology*, 35(2), 204-207.
- Bless, H., & Schwarz, N. (1999). Sufficient and necessary conditions in dual-process models. In S. Chaiken & Y. Trope (Eds.), *Dual-process theories in social psychology* (pp. 423-440). New York: The Guilford Press.
- Bollen, K. A. (1989). *Structural equations with latent variables*. New York: John Wiley.
- Brashers, D. E. (2001). Communication and uncertainty management. *Journal of Communication*, 51, 477-497.
- Brashers, D. E., Goldsmith, D. J., & Hsieh, E. (2002). Information Seeking and Avoiding in Health Contexts. *Human Communication Research*, 28(2), 258-271.
- Brody, J. (2008). Crisis of Care on the Front Line of Health. *The New York Times*, p. F7.
- Cacioppo, J. T., & Berntson, G. G. (1994). Relationship between attitudes and evaluative space: A critical review, with emphasis on the separability of positive and negative substrates. *Psychological Bulletin*, 115, 401-423.

- Cameron, L., Leventhal, E. A., & Leventhal, H. P. (1995). Seeking Medical Care in Response to Symptoms and Life Stress. *Psychosomatic Medicine*, 57(1), 37-47.
- Campbell, D. T., & Fiske, D. W. (1959). Convergent and discriminant validation by the multitrait-multimethod matrix. *Psychological Bulletin*, 56(2), 81-105.
- Carmines, E. G., & Zeller, R. A. (1979). *Reliability and validity assessment*. Beverly Hills, CA: Sage.
- Case, D. O. (2002). *Looking for information: A survey of research on information seeking, needs, and behavior*. San Diego, CA: Academic Press.
- Cassileth, B. R., Zupkis, R. V., Sutton-Smith, K., & March, V. (1980). Information and participation preferences among cancer patients. *Annals of Internal Medicine*, 92, 832-836.
- Castel, P., Negrier, S., & Boissel, J. P. (2006). Why don't cancer patients enter clinical trials? A review. *European Journal of Cancer*, 42(12), 1744-1748.
- Catania, C., De Pas, T., Goldhirsch, A., Radice, D., Adamoli, L., Medici, M., et al. (2008). Participation in clinical trials as viewed by the patient: Understanding cultural and emotional aspects which influence choice. *Oncology*, 74(3-4), 177-187.
- Chaffee, S. H. (1986). Mass media and interpersonal channels: Competitive, convergent, or complementary? In G. Gumpert & R. Cathcart (Eds.), *InterMedia* (3rd ed., pp. 62-80). New York: Oxford University Press.
- Chaiken, S. (1980). Heuristic versus systematic information processing and the use of source versus message cues in persuasion. *Journal of Personality and Social Psychology*, 39, 752-766.
- Chaiken, S., Liberman, A., & Eagly, A. H. (1989). Heuristic and systematic information processing within and beyond the persuasion context. In J. S. Uleman & J. A. Bargh (Eds.), *Unintended thought* (pp. 212-252). New York: Guilford Press.

- Chaiken, S., & Stangor, C. (1987). Attitude and attitude change. *Annual Review of Psychology*, 38, 575-630.
- Charles, C., Gafni, A., & Whelan, T. (1999). Decision-making in the physician-patient encounter: revisiting the shared treatment decision-making model. *Social Science & Medicine*, 49(5), 651-661.
- Chen, S., & Chaiken, S. (1999). The heuristic-systematic model in its broader context. In S. Chaiken & Y. Trope (Eds.), *Dual-process theories in social psychology* (pp. 73-96). New York: Guilford.
- Clarke, A., Shim, J. K., Mamo, L., Fosket, J. R., & Fishman, J. R. (2003). Biomedicalization: Technoscientific transformations of health, illness, and U.S. biomedicine. *American Sociological Review*, 68(2), 161-194.
- Clore, G. L., Schwarz, N., & Conway, M. (1994). Affective causes and consequences of social information processing. In J. Wyer, R. S. & T. K. Srull (Eds.), *Handbook of social cognition* (2nd ed., pp. 323-417). Hillsdale, NJ: Lawrence Erlbaum Associates.
- Cohen, J., Cohen, P., West, S. G., & Aiken, L. S. (2003). *Applied Multiple Regression/Correlation Analysis for the Behavioral Sciences* (3rd ed.). Mahwah, N.J.: Erlbaum Associates.
- Cohen, L., de Moor, C., & Amato, R. (2001). The association between treatment-specific optimism and depressive symptomatology in patients enrolled in a phase I cancer clinical trial. *Cancer*, 91, 1949-1955.
- Comis, R. L., Miller, J. D., Aldige, C. R., Krebs, L., & Stoval, E. (2003). Public attitudes toward participation in cancer clinical trials. *Journal of Clinical Oncology*, 21(5), 830-835.
- Cox, K. (2002). Informed consent and decision-making: patients' experiences of the process of recruitment to phases I and II anti-cancer drug trials. *Patient Education and Counseling*, 46(1), 31-38.
- Crosson, K., Eisner, E., Brown, C., & Maat, J. T. (2001). Primary care physicians' attitudes, knowledge, and practices. *Journal of Cancer Education*, 16(4), 188-192.

- Curbow, B., Fogarty, L. A., McDonnell, K. A., Chill, J., & Scott, L. B. (2006). The role of physician characteristics in clinical trial acceptance: Testing pathways of influence. *Journal of Health Communication, 11*, 199-218.
- Daugherty, C., Ratain, M. J., Grochowski, E., Stocking, C., Kodish, E., Mick, R., et al. (1995). Perceptions of cancer patients and their physicians involved in phase-I trials. *Journal of Clinical Oncology, 13*(5), 1062-1072.
- Davis, S. W., Nealon, E. O. D., & Stone, J. (1993). Evaluation of the National Cancer Institute's clinical trials booklet. *Journal of the National Cancer Institute Monographs, 14*, 139-145.
- Degner, L. F., Kristjanson, L. J., Bowman, D., Sloan, J. A., Carriere, K. C., O'Neil, J., et al. (1997). Information needs and decisional preferences in women with breast cancer. *JAMA, 277*(18), 1485-1492.
- Dijksterhuis, A., Bos, M. W., Nordgren, L. F., & Van Baaren, R. B. (2006). On making the right choice: The deliberation-without-attention effect. *Science, 311*, 1005-1007.
- Eagly, A., & Chaiken, S. (1993). *The psychology of attitudes*. Fort Worth, TX: Harcourt Brace and Jovanovich.
- Ellis, P. M. (2000). Attitudes towards and participation in randomised clinical trials in oncology: a review of the literature. *Annals of Oncology, 11*(8), 939-945.
- Ellis, P. M., Butow, P. N., Tattersall, M. H. N., Dunn, S. M., & Houssami, N. (2001). Randomized clinical trials in oncology: Understanding and attitudes predict willingness to participate. *Journal of Clinical Oncology, 19*(15), 3554-3561.
- Epstein, S. (2003). Inclusion, diversity, and biomedical knowledge making: the multiple politics of representation. In N. Oudschoorn & T. Pinch (Eds.), *How Users Matter: The Co-Construction of Users and Technology* (pp. 174-190). Cambridge, MA: MIT Press.
- Epstein, S. (2007). *Inclusion: the politics of difference in medical research*. Chicago: The University of Chicago Press.

- Fallowfield, L. J., Ford, S., & Lewis, S. (1995). No news is not good news: Information preferences of patients with cancer. *Psycho-Oncology*, 4, 197-202.
- Fallowfield, L. J., Ratcliffe, D., & Souhami, R. (1997). Clinicians' attitudes to clinical trials of cancer therapy. *European Journal of Cancer*, 33(13), 2221-2229.
- Fallowfield, L. J., Jenkins, V., Brennan, C., Sawtell, M., Moynihan, C., & Souhami, R. L. (1998). Attitudes of patients to randomised clinical trials of cancer therapy. *European Journal of Cancer*, 34(10), 1554-1559.
- Fazio, R. H. (1986). How do attitudes guide behavior? In R. M. H. Sorrentino & E. T. Higgins (Eds.), *Handbook of motivation and cognition: Foundations of social behavior* (pp. 204-243). New York: Guilford.
- Finucane, M. L., & Holup, J. (2006). Risk as value: Combining affect and analysis in risk judgments. *Journal of Risk Research*, 9(2), 141-164.
- Fishbein, M. (2007). A reasoned action approach: Some issues, questions, and clarifications. In I. Ajzen, D. Albarracin & R. Hornik (Eds.), *Prediction and change of health behavior: Applying the reasoned action approach*. Mahwah, NJ: Lawrence Erlbaum Associates.
- Fredrickson, B. L. (2001). The role of positive emotions in positive psychology: The broaden-and-build theory of positive emotions. *American Psychologist*, 56, 218-226.
- Fredrickson, B. L. (2005). Positive emotions. In C. R. Snyder & S. J. Lopez (Eds.), *Handbook of positive psychology* (pp. 120-134). New York, NY: Oxford University Press.
- Frijda, N. H., Kuipers, P., & ter Schure, E. (1989). Relations among emotion, appraisal, and emotional action readiness. *Journal of Personality and Social Psychology*, 57(2), 212-228.
- Garrity, T. F., & Lawson, E. J. (1989). Patient-physician communication as a determinant of medication misuse in older, minority women. *Journal of Drug Issues*, 19, 245-259.

- Giuliano, A. R., Mokuau, N., Hughes, C., Tortolero-Luna, G., Risendal, B., Ho, R. C. S., et al. (2000). Participation of minorities in cancer research: The influence of structural, cultural, and linguistic factors. *Annals of Epidemiology*, 10(8), S22-S34.
- Gordon, E. F., & Daugherty, C. K. (2001). Referral and decision making among advanced cancer patients participating in phase I trials at a single institution. *Journal of Clinical Ethics*, 12, 37-38.
- Grady, C., Hampson, L. A., Wallen, G. R., Rivera-Goba, M. V., Carrington, K. L., & Mittleman, B. B. (2006). Exploring the ethics of clinical research in an urban community. *American Journal of Public Health*, 96(11), 1996-2001.
- Grant, C. H., Cissna, K. N., & Rosenfeld, L. B. (2000). Patients' perceptions of physicians communication and outcomes of the accrual to trial process. *Health Communication*, 12(1), 23-39.
- Gregory, R., & Mendelsohn, R. (1993). Perceived risk, dread, and benefits. *Risk Analysis*, 13, 259-264.
- Griffin, R. J., Yang, Z., Boerner, F., Bourassa, S., Darrah, T., Knurek, S., Ortiz, S., & Dunwoody, S. (2005). *Applying an information seeking and processing model to a study of communication about energy*. Paper presented at the Association for Education in Journalism and Mass Communication annual convention, San Antonio, TX.
- Griffin, R. J., Dunwoody, S., & Neuwirth, K. (1999). Proposed model of the relationship of information seeking and processing to the development of preventive behaviors. *Environmental Research*, 80, S230-245.
- Griffin, R. J., Neuwirth, K., Dunwoody, S., & Giese, J. (2004). Information sufficiency and risk communication. *Media Psychology*, 6, 23-61.
- Griffin, R. J., Neuwirth, K., Giese, J., & Dunwoody, S. (2002). Linking the heuristic-systematic model and depth of processing. *Communication Research*, 29, 705-732.
- Griffin, R. J., Powell, M., Dunwoody, S., Neuwirth, K., Clark, D., & Novotny, V. (2004). *Testing the robustness of a risk information processing model*. Paper

presented at the Association for Education in Journalism and Mass
Communication annual convention, Toronto, Ontario, Canada

Griffin, R. J., Yang, Z., Huurne, E., Boerner, F., Ortiz, S., & Dunwoody, S. (2008).
After the Flood: Anger, Attribution, and the Seeking of Information. *Science
Communication*, 29(3), 285-315.

Guttman, N., & Ressler, W. H. (2001). On being responsible: Ethical issues in appeals
to personal responsibility in health campaigns. *Journal of Health
Communication*, 6, 117-136.

Harris, K. A. (1998). The informational needs of patients with cancer and their
families. *Cancer Practice*, 6(1), 39-46.

Harris, Y., Gorelick, P. B., Samuels, P., & Bempong, I. (1996). Why African
Americans may not be participating in clinical trials. *Journal of the National
Medical Association*, 88(10), 630-634.

Hilgartner, S. (1992). The social construction of risk objects: Or, how to pry open
networks of risk. In J. F. Short & L. Clarke (Eds.), *Organizations,
Uncertainties, and Risk* (pp. 39-53). Boulder, CO: Westview Press.

Howerton, M. W., Gibbons, M. C., Baffi, C. R., Gary, T. L., Lai, G. Y., Bolen, S., et
al. (2007). Provider roles in the recruitment of underrepresented populations to
cancer clinical trials. *Cancer*, 109(3), 465-476.

Hutchison, C., & Campbell, S. (2002). Evaluation of an information booklet for
patients considering participation in phase I clinical trials in cancer. *European
Journal of Cancer Care*, 11(2), 131-138.

Huurne, E. F. J., Griffin, R. J., & Gutteling, J. M. (2009). Risk information seeking
among U.S. and Dutch residents. *Science Communication*.

Isen, A. M. (1987). Positive affect, cognitive processes, and social behavior. In L.
Berkowitz (Ed.), *Advances in Experimental Social Psychology* (Vol. 20, pp.
203-253). San Diego, CA: Academic Press.

- Isen, A. M. (1999). Positive Affect. In T. P. Dalgleish, M. J. (Ed.), *Handbook of cognition and emotion* (pp. 521-538). Chichester, England: John Wiley & Sons.
- Isen, A. M. (2004). Some perspectives on positive feelings and emotions: Positive affect facilitates thinking and problem solving. In A. S. R. Manstead, N. Frijda & A. Fischer (Eds.), *Feelings and Emotions: The Amsterdam Symposium* (pp. 263-281). New York: Cambridge.
- Ito, T. A., & Cacioppo, J. T. (2005). Variations on a human universal: Individual differences in positivity offset and negativity bias. *Cognition and Emotion*, 19(1), 1-26.
- James, N., Daniels, H., Rahman, R., McConkey, C., Derry, J., & Young, A. (2007). A study of information seeking by cancer patients and their carers. *Clinical Oncology*, 19, 356-362.
- Jenkins, V. A., & Fallowfield, L. J. (2000). Reasons for accepting or declining to participate in randomized clinical trials for cancer therapy. *British Journal of Cancer*, 82(11), 1783-1788.
- Jenkins, V. A., Fallowfield, L. J., Souhami, A., & Sawtell, M. (1999). How do doctors explain randomised clinical trials to their patients? *European Journal of Cancer*, 35(8), 1187-1193.
- Jensen, A. B., Madsen, B., Andersen, P., & Rose, C. (1993). Information for cancer patients entering a clinical trial--an evaluation of an information strategy. *European Journal of Cancer*, 29(16), 2235-2238.
- Johnson, J. D. (1997). *Cancer-related information seeking*. Cresskill, NJ: Hampton Press, Inc.
- Johnson, J. D., & Meishcke, H. (1992). Differences in evaluating of communication channels for cancer-related information. *Journal of Behavioral Medicine*, 15(5), 429-445.
- Jones, J. M., Nyhof-Young, J., Moric, J., Friedman, A., Wells, W., & Catton, P. (2006). Identifying motivations and barriers to patient participation in clinical trials. *Journal of Cancer Education*, 21(4), 237-242.

- Jöreskog, K. G., & Sörbom, D. (1996a). *PRELIS 2: User's reference guide*. Chicago: Scientific Software International.
- Jöreskog, K. G., & Sörbom, D. (1996b). *LISREL 8: User's reference guide*. Chicago: Scientific Software International.
- Kahlor, L., Dunwoody, S., & Griffin, R. J. (2002). Attributions in explanations of risk estimates. *Public Understanding of Science*, 11, 243-257.
- Kahlor, L. (2007). An augmented risk information seeking model: The case of global warming. *Media Psychology*, 10, 414-435.
- Kahlor, L., Dunwoody, S., Griffin, R. J., & Neuwirth, K. (2006). Seeking and processing information about impersonal risk. *Science Communication* 28(2), 163-194.
- Kahlor, L., Dunwoody, S., Griffin, R. J., Neuwirth, K., & Giese, J. (2003). Studying heuristic-systematic processing of risk communication. *Risk Analysis*, 23, 355-368.
- Kahlor, L., & Rosenthal, S. (2009). If we seek, do we learn? Predicting knowledge of global warming. *Science Communication*, 30(3), 380-414.
- Kahneman, D., Slovic, P., & Tversky, A. (1982). *Judgement under uncertainty: Heuristics and biases*. New York: Cambridge University Press.
- Katz, E., Blumler, J. G., & Gurevitch, M. (1974). Utilization of mass communication by the individual. In J. G. Blumler & E. Katz (Eds.), *The uses of mass communication: Current perspectives on gratifications research* (pp. 19-32). Beverly Hills, CA: Sage.
- Kline, R. B. (2005). *Principles and practice of structural equation modeling* (2nd ed.). New York: Guilford Press.
- Kodish, E., Eder, M., Noll, R. B., Ruccione, K., Lange, B., Angiolillo, A., et al. (2004). Communication of randomization in childhood leukemia trials. *JAMA*, 291(4), 470-475.

- Kodish, E., & Post, S. G. (1995). Oncology and hope. *Journal of Clinical Oncology*, 13, 1817-1822.
- Kosicki, G. M. & McLeod, J. M. (1990). Learning from political news: Effects of media images and information processing strategies. In S. Kraus (Ed.), *Mass Communication and Political Information Processing* (pp. 69-83). Hillsdale, NJ: Erlbaum.
- Krupat, E., & Irish, J. T. (2007). Cancer patients as active participants in their care. In H. D. O'Hair, G. L. Kreps & L. Sparks (Eds.), *Handbook of communication and cancer care*. Cresskill, NJ: Hampton Press.
- Lara, P. N., Jr., Higdon, R., Lim, N., Kwan, K., Tanaka, M., Lau, D. H. M., et al. (2001). Prospective Evaluation of Cancer Clinical Trial Accrual Patterns: Identifying Potential Barriers to Enrollment. *Journal of Clinical Oncology*, 19(6), 1728-1733.
- Lara, P. N., Jr., Paterniti, D. A., Chiechi, C., Turrell, C., Morain, C., Horan, N., et al. (2005). Evaluation of Factors Affecting Awareness of and Willingness to Participate in Cancer Clinical Trials. *Journal of Clinical Oncology*, 23(36), 9282-9289.
- Lazarus, R. S. (2006). Emotions and interpersonal relationships: Toward a person-centered conceptualization of emotions and coping. *Journal of Personality*, 74(1), 9-46.
- Lazarus, R. S., & Folkman, S. (1984). *Stress, appraisal, and coping*. New York, NY: Springer Publishing Company, Inc.
- Lemire, M., Paré, G., Sicotte, C., & Harvey, C. (2008). Determinants of Internet use as a preferred source of information on personal health. *International Journal of Medical Informatics*, 77, 723-734.
- Lerman, C., Daly, M., Walsh, W. P., Resch, N., Seay, J., Barsevick, A., et al. (1993). Communication between patients with breast cancer and health care providers: Determinants and implications. *Cancer*, 72(9), 2612-2620.
- Lerner, J. S., & Keltner, D. (2001). Fear, anger, and risk. *Journal of Personality and Social Psychology* 81, 146-159.

- Leventhal, H. (1970). Findings and theory in the study of fear communications. In L. Berkowitz (Ed.), *Advances in Experimental Social Psychology* (Vol. 5, pp. 119-186). New York: Academic Press.
- Leydon, G. M., Boulton, M., Moynihan, C., Jones, A., Mossman, J., Boudioni, M., et al. (2008). Cancer patients' information needs and information seeking behaviour: in depth interview study. *British Medical Journal*, 320, 909-913.
- Linden, H. M., Reisch, L. M., Hart Jr., A., Harrington, M. A., Nakano, C., Jackson, J. C., et al. (2007). Attitudes toward participation in breast cancer randomized clinical trials in the African American community: a focus group study. *Cancer Nursing*, 30(4), 261-269.
- Llewellyn-Thomas, H. A., McGreal, M. J., Thiel, E. C., & et al. (1991). Patients' willingness to enter clinical trials: measuring the association with perceived benefit and preference for decision participation. *Social Science & Medicine*, 32(1), 35-42.
- Loewenstein, G. F., Weber, E. U., Hsee, C. K., & Welch, N. (2001). Risk as Feelings. *Psychological Bulletin*, 127(2), 267-286.
- MacKenzie, D. (1998). The certainty trough. In R. Williams, W. Faulkner & J. Fleck (Eds.), *Exploring expertise* (pp. 325-329). Houndmills, UK: Macmillan.
- Madsen, S. M., Holm, S., & Riis, P. (2007). Attitudes towards clinical research among cancer trial participants and non-participants: an interview study using a Grounded Theory approach. *Journal of Medical Ethics*, 33(4), 234-240.
- Madsen, S. M., Mirza, M. R., Holm, S., Hilsted, K. L., Kampmann, K., & Riis, P. (2002). Attitudes towards clinical research amongst participants and nonparticipants. *Journal of Internal Medicine*, 251(2), 156-168.
- Mancini, J., Geneve, J., Dalenc, F., Genre, D., Monnier, A., Kerbrat, P., et al. (2007). Decision-making and breast cancer clinical trials - How experience challenges attitudes. *Contemporary Clinical Trials*, 28(6), 684-694.
- Mannel, R. S., Walker, J. L., Gould, N., Scribner, D. R., Kamelle, S., Tillmanns, T., et al. (2003). Impact of individual physicians on enrollment of patients into clinical trials. *American Journal of Clinical Oncology-Cancer Clinical Trials*, 26(2), 171-173.

- McComas, K. A., Yang, Z., Gay, G. K., Leonard, J. P., Dannenberg, A. J., & Dillon, H. (forthcoming). Individuals' willingness to talk to their doctors about clinical trial enrollment. *Journal of Health Communication*.
- McGuire, W. J. (1974). Psychological motives and communication gratification. In J. G. Blumler & E. Katz (Eds.), *The uses of mass communications: Current perspectives on gratifications research* (pp. 167-198). Beverly Hills, CA: Sage.
- Meropol, N. J., Buzaglo, J. S., Millard, J., Damjanov, N., Miller, S. M., Ridgway, C., et al. (2007). Barriers to clinical trial participation as perceived by oncologists and patients. *Journal of the National Comprehensive Cancer Network*, 5(8), 655-664.
- Mettlin, C., Cummings, K. M., & Walsh, D. (1985). Risk factor and behavioral correlates of willingness to participate in cancer prevention trials. *Nutrition in Cancer Care*, 7(4), 189-198.
- Mieg, H. A. (2001). *The social psychology of expertise: Case studies in research, professional domains, and expert roles*. Mahwah, NJ: Lawrence Erlbaum Associates.
- Miller, S. M. (1989). Cognitive informational styles in the process of coping with threat and frustration. *Advances in Behavior Research and Therapy*, 77, 223-234.
- Miller, S. M., Shoda, Y., & Hurley, K. (1996). Applying cognitive-social theory to health-protective behavior: Breast self-examination in cancer screening. *Psychological Bulletin* 119(1), 70-94.
- Mills, E. J., Seely, D., Rachlis, B., Griffith, L., Wu, P., Wilson, K., et al. (2006). Barriers to participation in clinical trials of cancer: a meta-analysis and systematic review of patient-reported factors. *Lancet Oncology*, 7(2), 141-148.
- National Cancer Institute. (2001). *Cancer clinical trials: the in-depth program*. Bethesda, MD.
- National Cancer Institute. (1997). *Boosting Cancer Trial Participation*. Bethesda, MD.

- National Institutes of Health, National Cancer Institute. (1997). *Results from Quarterly Omnibus Survey: Clinical Trials Questions*. Bethesda, MD.
- National Institutes of Health, National Cancer Institute, Working Group on Enhancing Recruitment to Early Phase Cancer Clinical Trials. (2004). *Enhancing Recruitment to Early Phase Cancer Clinical Trials: Literature Review*. Bethesda, MD.
- Nelson, W. L., Han, P. K. J., Fagerlin, A., Stefanek, M., & Ubel, P. A. (2007). Rethinking the Objectives of Decision Aids: A Call for Conceptual Clarity. *Medical Decision Making*, 27(5), 609-618.
- Niederdeppe, J., Frosch, D. L., & Hornik, R. C. (2008). Cancer news coverage and information seeking. *Journal of Health Communication*, 13(2), 181-199.
- Niederdeppe, J., Hornik, R. C., Kelly, B. J., Frosch, D. L., Romantan, A., Stevens, R. S., et al. (2007). Examining the dimensions of cancer-related information seeking and scanning Behavior. *Health Communication*, 22(2), 153-167.
- Nisbett, R., Borgida, E., Crandall, R., & Reed, H. (1976). Popular induction: Information is not necessarily informative. In J. S. Carroll & J. Payne (Eds.), *Cognition and social behavior*. Hillsdale, NJ: Erlbaum.
- Nowotny, M. L. (1991). Every tomorrow, a vision of hope. *Journal of Psychosocial Oncology*, 9(3), 117-126.
- Nurgat, Z. A., Craig, W., Campbell, N. C., Bissett, J. D., Cassidy, J., & Nicolson, M. C. (2005). Patient motivations surrounding participation in phase I and phase II clinical trials of cancer chemotherapy. *British Journal of Cancer*, 92(6), 1001-1005.
- Ortony, A., & Clore, G. L. (1981). *Disentangling the affective lexicon*. Paper presented at the Third Annual Conference of the Cognitive Science Society, Berkeley, CA.
- Parker-Pope, T. (2008). You're Sick. Now What? Knowledge Is Power. *The New York Times*, p. F1.

- Peel, E., Parry, O., Douglas, M., & Lawton, J. (2006). "It's no skin off my nose": Why people take part in qualitative research. *Qualitative Health Research*, 16(10), 1335-1349.
- Pentz, R. D., Flamm, A. L., Sugarman, J., Cohen, M. Z., Ayers, G. D., Herbst, R. S., et al. (2002). Study of the media's potential influence on prospective research participants' understanding of and motivations for participation in a high-profile phase I trial. *Journal of Clinical Oncology*, 20(18), 3785-3791.
- Petersen, S., Heesacker, M., & Marsh, R. D. (2001). Medical decision making among cancer patients. *Journal of Counseling Psychology*, 48(2), 239-244.
- Petty, R. E., & Cacioppo, J. T. (1986). *Communication and persuasion: Central and peripheral routes to attitude change*. New York: Springer-Verlag.
- Raghunathan, R., & Pham, M. T. (1999). All negative moods are not equal: Motivational influences of anxiety and sadness on decision making. *Organizational Behavior and Human Decision Processes*, 79(1), 56-77.
- Rimal, R. N., & Real, K. (2003). Understanding the influence of perceived norms on behaviors. *Communication Theory*, 13(2), 184-203.
- Roberson, N. L. (1994). Clinical trial participation - Viewpoints from racial/ethnic groups. *Cancer*, 74(9), 2687-2691.
- Rogers, E. M. (2002). Intermedia processes and powerful media effects. In J. Bryant & D. Zillmann (Eds.), *Media effects: Advances in theory and research* (pp. 199-214). Mahwah, NJ: Lawrence Erlbaum Associates.
- Romantan, A., Hornik, R., Price, V., Cappella, J., & Viswanath, K. (2008). A comparative analysis of the performance of alternative measures of exposure. *Communication Methods and Measures*, 2(1-2), 80-99.
- Rotter, J. B. (1954). *Social learning and clinical psychology*. Englewood Cliffs, NJ: Prentice-Hall.
- Ryan, J., & Sysko, J. (2007). The contingency of patient preferences for involvement in health decision making. *Health Care Management Review*, 32(1), 30-36.

- Sardell, A. N., & Trierweiler, S. J. (1993). Disclosing the cancer diagnosis: Procedures that influence patient hopefulness. *Cancer*, 72(11), 3355-3365.
- Schain, W. S. (1994). Barriers to clinical trials. Part II: Knowledge and attitudes of potential participants. *Cancer*, 74(S9), 2666-2671.
- Scheier, M. F., & Carver, C. S. (1992). Effects of optimism on psychological and physical well-being: Theoretical overview and empirical update. *Cognitive Therapy and Research*, 16(2), 201-228.
- Schemer, C., Matthes, J., & Wirth, W. (2008). Toward improving the validity and reliability of media information processing measures in surveys. *Communication Methods and Measures*, 2(3), 193-225.
- Schwarz, N., & Bless, B. (1991). Happy and mindless, but sad and smart? The impact of affective states on analytic reasoning. In J. Forgas (Ed.), *Emotion and social judgment* (pp. 55-71). Oxford, UK: Pergamon Press.
- Schwarz, N., & Bohner, G. (1996). Feelings and their motivational implications. In P. M. Gollwitzer & J. A. Bargh (Eds.), *The psychology of action: Linking cognition and motivation to behavior* (pp. 119-145). New York: The Guilford Press.
- Schwarz, N., & Clore, G. L. (1988). How do I feel about it? Informative functions of affective states. In K. Fiedler & J. Forgas (Eds.), *Affect, cognition and social behavior* (pp. 44-62). Toronto: Hogrefe.
- Schwarzer, R. (1994). Optimism, vulnerability, and self-beliefs as health-related. *Psychology & Health*, 9, 161-180.
- Sharf, B. F. & Street, Jr., R. L. (1997). The Patient as a Central Construct: Shifting the Emphasis. *Health Communication*, 9, 1-11.
- Sharma, R. A., Symonds, R. P., O'Byrne, K. J., Cheater, F., Abrams, K. R., & Steward, W. P. (2001). Involving patients in treatment decisions: Can we learn from clinical trials? *Clinical Oncology*, 13(5), 328-332.
- Sharp, L., Cotton, S. C., Alexander, L., Williams, E., Gray, N. M., & Reid, J. M. (2006). Reasons for participation and non-participation in a randomized

controlled trial: postal questionnaire surveys of women eligible for TOMBOLA (Trial of Management of Borderline and Other Low-grade Abnormal smears). *Clinical Trials*, 3(5), 431-442.

Siegrist, M., Cvetkovich, G., & Roth, C. (2000). Salient value similarity, social trust, and risk/benefit perception. *Risk Analysis*, 17, 115-124.

Siminoff, L. A., & Thomas, T. A. (2008). Why learning to communicate with our patients is so important: Using communication to enhance accrual to cancer clinical trials. *Journal of Clinical Oncology*, 26(16), 2614-2615.

Slovic, P. (1992). Perception of risk: Reflections on the psychometric paradigm. In S. Krimsky & D. Golding (Eds.), *Social Theories of Risk* (pp. 117-152). Westport, CT: Praeger.

Slovic, P., Peters, E., Finucane, M. L., & MacGregor, D. G. (2005). Affect, risk, and decision making. *Health Psychology*, 24(4), S35-40.

Somkin, C. P., Altschuler, A., Ackerson, L., Geiger, A. M., Greene, S. M., Mouchawar, J., et al. (2005). Organizational barriers to physician participation in cancer clinical trials. *American Journal of Managed Care*, 11(7), 413-421.

Stryker, J. E., Wray, R. J., Emmons, K. M., Winer, E., & Demetri, G. (2006). Understanding the decisions of cancer clinical trial participants to enter research studies: Factors associated with informed consent, patient satisfaction, and decisional regret. *Patient Education and Counseling*, 63(1-2), 104-109.

Sutherland, H. J., Llewellyn-Thomas, H. A., Lockwood, G. A., Trichter, D. L., & Till, J. E. (1989). Cancer patients: Their desire for information and participating in treatment decisions. *Journal of the Royal Society of Medicine*, 82(5), 260-263.

Taylor, S. E. (1983). Adjustment to threatening events: A theory of cognitive adaptation. *American Psychologist*, 38(11), 1161-1173.

Taylor, S. E., Kemeny, M. E., Reed, G. M., Bower, J. E., & Gruenewald, T. L. (2000). Psychological resources, positive illusions, and health. *American Psychologist*, 55(1), 99-109.

- Taylor, S. E., Lichtman, R. R., & Wood, J. V. (1984). Attributions, beliefs about control, and adjustment to breast cancer. . *Journal of Personality and Social Psychology*, 46(3), 489-502.
- Thorne, S., Hislop, T. G., Kuo, M., & Armstrong, E.-A. (2006). Hope and Probability: Patient Perspectives of the Meaning of Numerical Information in Cancer Communication. *Qualitative Health Research*, 16(3), 318-336.
- Thorne, S. E., Hislop, T. G., Armstrong, E. A., & Oglov, V. (2008). Cancer care communication: The power to harm and the power to heal. *Patient Education and Counseling*, 71(1), 34-40.
- Tiedens, L. Z., & Linton, S. (2001). Judgment under emotional certainty and uncertainty: The effects of specific emotions on information processing. *Journal of Personality and Social Psychology*, 81(6), 973-988.
- Trauth, J. M., Musa, D., Siminoff, L., Jewell, I. K., & Ricci, E. (2000). Public attitudes regarding willingness to participate in medical research studies. *Journal of Health & Social Policy*, 12(2), 23-43.
- Trope, Y., & Neter, E. (1994). Reconciling competing motives in self-evaluation: The role of self-control in feedback seeking. *Journal of Personality and Social Psychology*, 66(4), 646-657.
- Trumbo, C. W. (2002). Information processing and risk perception: An adaptation of the heuristic-systematic model. *Journal of Communication*, 52(2), 367-382.
- Tversky, A., & Kahneman, D. (1974). Judgment under Uncertainty: Heuristics and Biases. *Science*, 185(4157), 1124-1131.
- Umutyan, A., Chiechi, C., Beckett, L. A., Paterniti, D. A., Turrell, C., Gandara, D. R., et al. (2008). Overcoming barriers to cancer clinical trial accrual: Impact of a mass media campaign. *Cancer*, 112(1), 212-219.
- van Luijn, H. E. M., Aaronson, N. K., Keus, R. B., & Musschenga, A. W. (2006). The evaluation of the risks and benefits of phase II cancer clinical trials by institutional review board (IRB) members: A case study. *Journal of Medical Ethics*, 32, 170-176.

- Verheggen, F. W. S. M., Jonkers, R., & Kok, G. (1996). Patients' perceptions on informed consent and the quality of information disclosure in clinical trials *Patient Education and Counseling*, 29, 137-153.
- Verheggen, F. W. S. M., Nieman, F., & Jonkers, R. (1998). Determinants of patient participation in clinical studies requiring informed consent: Why patients enter a clinical trial. *Patient Education and Counseling*, 35, 111-125.
- Viswanath, K., & Finnegan, R. (1995). The knowledge gap hypothesis: Twenty-five years later. In B. Burleson (Ed.), *Communication yearbook* (Vol. 19, pp. 187-228). Thousand Oaks, CA: Sage.
- Weinstein, N. D. (1989). Optimistic biases about personal risks. *Science*, 246, 1232-1233.
- Witte, K. (1994). Fear control and danger control: An empirical test of the extended parallel process model. *Communication Monographs*, 61, 113-134.
- Wright, J. R., Crooks, D., Ellis, P. M., Mings, D., & Whelan, T. J. (2002). Factors that influence the recruitment of patients to phase III studies in oncology - The perspective of the clinical research associate. *Cancer*, 95(7), 1584-1591.
- Wright, J. R., Whelan, T. J., Schiff, S., Dubois, S., Crooks, D., Haines, P. T., et al. (2004). Why cancer patients enter randomized clinical trials: Exploring the factors that influence their decision. *Journal of Clinical Oncology*, 22(21), 4312-4318.
- Yeomanskinney, A., Vernon, S. W., Frankowski, R. F., Weber, D. M., Bitsura, J. M., & Vogel, V. G. (1995). Factors related to enrollment in the breast-cancer prevention trial at a comprehensive cancer center during the first year of recruitment. *Cancer*, 76(1), 46-56.